

U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER: (ixg)

FOLDER: K043065 - 1145 pages (FOI:08008281)

COMPANY: EDWARDS LIFESCIENCES, LLC. (EDWALIFE)

PRODUCT: TRANSDUCER, BLOOD-PRESSURE, EXTRAVASCULAR (DRS)

SUMMARY: Product: VIGILEO ARTERIAL PRESSURE CARDIAC

OUTPUT/OXIMETRY MONITOR, MODELS MIHM

DATE REQUESTED: Oct 8, 2010

DATE PRINTED: Nov 16, 2011

Note: Releasable Version



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JAN 2 6 2005

p1/4

510(k) Summary

Submitter:

Edwards Lifesciences LLC

One Edwards Way

Irvine, CA 92614-5686

Contact Person:

Jason Smith, Senior Regulatory Affairs Specialist

Date Prepared:

November 4, 2004

Trade names:

Vigileo Arterial Pressure Cardiac Output/Oximetry

(APCO/Oximetry) Monitor

Edwards Dual Disposable Pressure Transducer (DDPT)

Classification

Monitor:

Name:

Single-Function, Preprogrammed Diagnostic Computer

(21 CFR 870.1435)

Transducer:

Extravascular Blood Pressure Transducer (21 CFR

870.2850)

Predicate Devices:

Monitor:

Vigilance Continuous Cardiac Output/Oximetry/Continuous

End Diastolic Volume (CCO/SvO₂/CEDV) Monitor

Metracor RODA Monitoring System

. Transducer: .

Phoenix Disposable Pressure Transducer

Device

Description:

The Vigileo APCO/Oximetry monitor is a microprocessor-based instrument which, when connected to a DDPT, continuously measures arterial pressure cardiac output

(APCO). When connected to an Edwards oximetry catheter, the monitor measures oxygen saturation (oximetry). The monitor also calculates other derived parameters including cardiac index, stroke volume, stroke volume index, stroke volume variation, system vascular resistance, and systemic

vascular resistance index.

Intended Use:

The Vigileo APCO/Oximetry monitor is intended to measure arterial pressure cardiac output and oximetry. The monitor

also calculates hemodynamic and oxygenation parameters.

The DDPT is intended to measure intravascular pressures. It is intended to transmit those pressure readings to both a standard blood pressure monitor and to the *Vigileo* monitor.

Comparative Analysis:

Both the Vigileo APCO/Oximetry monitor and the DDPT have been demonstrated to be as safe and effective as the

predicate devices for their intended uses.

10-5005 1-272

Functional/Safety

Testing:

Both the Vigileo APCO/Oximetry Monitor and the DDPT

have successfully undergone functional testing as well as

electrical safety testing. They have been shown to be

equivalent to the predicate devices.

Conclusion:

The Vigileo APCO/Oximetry Monitor and DDPT are

substantially equivalent to the predicate devices.

ason Smith

Senior Regulatory Affairs Specialist

Edwards Lifesciences LLC

Date -



JAN 2 6 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Edwards Lifesciences LLC c/o Mr. Jason Smith Senior Regulatory Affairs Specialist One Edwards Way Irvine, CA 92614

Re: K043065

Trade Name: Vigileo APCO/Oximetry Monitor, Models MIHM1 and MIHM1P

Regulation Number: 21 CFR 870.1435 and 21 CFR 870.2850

Regulation Name: Single-Function, Preprogrammed Diagnostic Computer and

Extravascular Blood Pressure Transducer

Regulatory Class: II (two) Product Code: DXG and DRS Dated: November 04, 2004 Received: November 05, 2004

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Page 2 - Mr. Jason Smith

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mynmuman for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if kn	own):		
Device Name:	Vigileo APC	O/Oximetry mo	nitor
Indications for Use:			
The <i>Vigileo</i> APCO/O hemodynamic parame and consumption.	ximetry monit eters such as ca	tor is indicated f ardiac output an	or use for continuously measuring doximetry to assess oxygen delivery
indicated for use in in	travascular pro	essure monitorir	sposable pressure transducer is ng. It is also indicated for use with oring devices or hardware to measur
Prescription Use _	_X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801	Subpart D)		(21 CFR 807 Subpart C)
(PLEASE DO PAGE IF NEEI		BELOW THIS	LINE-CONTINUE ON ANOTHER
Conc	urrence of CD	PRH, Office of I	Device Evaluation (ODE)
AMMINE On Sign-Off)		<u> </u>	Page 1 of £
On of Cardiovascul	Or Devices		



JAN 2 6 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Edwards Lifesciences LLC c/o Mr. Jason Smith Senior Regulatory Affairs Specialist One Edwards Way Irvine, CA 92614

Re: K043065

Trade Name: Vigileo APCO/Oximetry Monitor, Models MIHM1 and MIHM1P

Regulation Number: 21 CFR 870.1435 and 21 CFR 870.2850

Regulation Name: Single-Function, Preprogrammed Diagnostic Computer and

Extravascular Blood Pressure Transducer

Regulatory Class: II (two)
Product Code: DXG and DRS
Dated: November 04, 2004
Received: November 05, 2004

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Page 2 – Mr. Jason Smith

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Nu	mber (if known):			
Device Na	ıme: Vigile	o APCO/Oximetr	y monitor	
Indications	s for Use:			
The <i>Vigile</i> hemodynar and consur	mic parameters suc	/ monitor is indica ch as cardiac outp	ated for use for conti ut and oximetry to a	nuously measuring ssess oxygen delivery
indicated for	or use in intravasci ulse pressure based	ular pressure mor	ial disposable pressi litoring. It is also in- nonitoring devices of	are transducer is dicated for use with r hardware to measure
	otion Use <u>X</u> CFR 801 Subpart		0 . 01 ,111	e-Counter Use 07 Subpart C)
	EASE DO NOT W	RITE BELOW T		UE ON ANOTHER
	Concurrence	of CDRH, Office	e of Device Evaluation	on (ODE)
Blymn	<u>mo</u>			Page 1 of
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Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation Document Mail Center (HFZ-401) 9200 Corporate Blvd. Rockville, Maryland 20850

November 05, 2004

EDWARDS LIFESCIENCES, LLC.

ONE EDWARDS WAY IRVINE, CA 92614 ATTN: JASON SMITH 510(k) Number: K043065

K043065 05-NOV-2004

Received: Product:

VIGILEO ARTERIAL

PRESSURE CARDIAC OUTPUT/OXIMETRY MONITOR, MODELS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman Supervisory Consumer Safety Officer Office of Device Evaluation Center for Devices and Radiological Health

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K043065

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Edwards

November 4, 2004

(b)(4)

Office of Device Evaluation 510(k) Document Mail Center (HFZ-401) Center for Devices and Radiological Health Food and Drug Administration 2900 Corprate Boulevard Rockville MD 28050

Sincerely,

Íason Smith

Senior Regulatory Affairs Specialist

Edwards Lifesciences

Premarket Notification Truthful and Accurate Statement*

(As required by 21 CFR 807.87(j))

I certify that, in my capacity as Senior Regulatory Affairs Specialist for Edwards Lifesciences LLC, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Jason Smite 1/14/04
[Signature]
Jason Smith
[Typed name]
November 4, 2004
[Date]
[Premarket Notification (510(k)) Number]

Page ___ of ___

^{*} Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

510(k) Number (if kn	own):		
Device Name:	Vigileo APC	O/Oximetry mor	nitor
Indications for Use:			
<u>~</u>	-		for use for continuously measuring doximetry to assess oxygen deliver
indicated for use in in	travascular pro	essure monitorir	sposable pressure transducer is ng. It is also indicated for use with oring devices or hardware to measur
Prescription Use _	_x ·	AND/OR	Over-The-Counter Use
(Part 21 CFR 801	Subpart D)		(21 CFR 807 Subpart C)
(PLEASE DO PAGE IF NEEI		BELOW THIS	LINE-CONTINUE ON ANOTHER
Conc	urrence of CE	DRH, Office of I	Device Evaluation (ODE)
			Page 1 of

Fc	orm Approved ON	MB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.			
DEPARTMENT OF HEALTH AND HUMAN SERVICES		(b)(4)			
FOOD AND DRUG ADMINISTRATION		IDENTIFICATION NUMBER:			
MEDICAL DEVICE USER FEE COVER SHEET		ayment Identification Number on your check.			
A completed Cover Sheet must accompany each original a properly submit your application and fee payment:	application or	supplement subject to fees. The following actions must be taken to			
 Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (<i>Note: In no case should payment be submitted with the application.</i>) If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: 					
http://www.fda.gov/cdrh/mdufma/faqs.html#3a. Yo 6. Include a copy of the completed Cover Sheet in v CDRH Document Mail Center.	ou are respor olume one of	nsible for paying all fees associated with wire transfers. If the application when submitting to the FDA at either the CBER or			
1. COMPANY NAME AND ADDRESS (Include name, streaddress, city, state, country, and post office code)	eet	2 CONTACT NAME (b)(4)			
EDWARDS LIFESCIENCES ONE EDWARDS WAY IRVINE. CA 92614	ļ	2.1 E-MAIL ADDRESS (b)(4)			
		2.2 TELEPHONE NUMBER (Include Area Code) (b)(4)			
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)		2.3 FACSIMILE (FAX) NUMBER (Include Area Code) (b)(4)			
3. TYPE OF PREMARKET APPLICATION (Select one of descriptions at the following web site: http://www.fda.gov/	the following oc/mdufma	in each column; if you are unsure, please refer to the application			
Select an application type: Yermarket notification (510(k)); except for third party	reviews	3.1 Select one of the types below: Original Application			
Biologics License Application (BLA)		Supplement Types:			
Premarket Approval Application (PMA)		☐ Efficacy (BLA)			
Modular PMA		Panel Track (PMA, PMR, PDP)			
Product Development Protocol (PDP)		Real-Time (PMA, PMR, PDP)			
Premarket Report (PMR)		180-day (PMA, PMR, PDP)			
	f				
4. ARE YOU A SMALL BUSINESS? (See the instructions					
☐ YES, I meet the small business criteria and have s required qualifying documents to FDA	ubmitted the	₩ NO, I am not a small business			
4.1 If Yes, please enter your Small Business Decision	Number:				
5. IS THIS PREMARKET APPLICATION COVERED BY A APPLICABLE EXCEPTION.	NY OF THE	FOLLOWING USER FEE EXCEPTIONS ? IF SO, CHECK THE			
This application is the first PMA submitted by a qual business, including any affiliates, parents, and partn		The sole purpose of the application is to support conditions of use for a pediatric population			
This biologics application is submitted under section Public Health Service Act for a product licensed for manufacturing use only		The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLIC PEDIATRIC POPULATION THAT NOW PROPOSES COI subject to the fee that applies for an original premarket ap	NDITION OF	USE FOR ANY ADULT POPULATION? (If so, the application is			
☐ YES ☑ NO					
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THE (b)(4)	HIS PREMAR	RKET APPLICATION (FOR FISCAL YEAR 2005)			
Form FDA 3601 (08/2003)					

24



Edwards

Edwards Lifesciences LLC 510(k) Notification for

Vigileo APCO/Oximetry monitor

Trade Name:

Vigileo Arterial Pressure Cardiac Output/Oximetry monitor

Model Numbers:

MIHM1, MIHM1P

Manufacturer:

Edwards Lifesciences LLC

Est. Regist. No.:

2015691

Classification Name:

Single-Function, Preprogrammed Diagnostic Computer

(21 CFR 870.1435)

Regulatory Class:

II

Date:

November 4, 2004

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Appendix J Software Requirements Specification

Appendix K Software Design Document

Appendix L Software Testing Reports

Appendix M Trace Matrix

Appendix N Mechanical and Environmental Testing Reports

Appendix O EMC Testing Report

Appendix P Reference Articles

I. General Information

A.	Product (Trade) Name					
	Vigileo APCO/Oximetry monitor					
	Model Numbers:					
	Edwards Dual Disposabl	e Pressure Trans	ducer (DDPT)			
	Model Number:	MHD002NCT				
В.	Common, Usual or Cla	ssification Nam	e			
	Monitor: Single-Functio	n, Preprogramm	ed Diagnostic Computer (21 CFR	L		
	870.1435)					
	DDPT: Extravascular Bl	ood Pressure Tr	ansducer (21 CFR 870.2850)			
C.	Establishment Registra	tion Numbers				
	Edwards (Irvine): 2015	591	(b)(4)			
	(b)(4)		•			
D.	Address of Manufactur	ers				
	Monitor:					
	Edwards Lifescience	es LLC	(b)(4)			
	One Edwards Way Irvine, CA 92614-5	686				
	DDPT:	000				
	Edwards Lifesciences LLC					
	One Edwards Way					
	Irvine, CA 92614-50	686				
	A 1 1 CC/- 'P' 4'	C'4- (DDDT am	1A			
	Address of Sterilization (b)(4)	Site (DDF1 on	uy)			



E. Device Classification

This generic device (*Vigileo* monitor) has been classified as Class II by the Circulatory System Device Panel (21 CFR 870.1435), product code DXG. The DDPT has been classified as Class II by the Circulatory System Device Panel (21 CFR 870.2850), product code DRS.

F. Reason for Submission

Edwards Lifesciences LLC intends to market the *Vigileo* Arterial Pressure Cardiac Output/Oximetry monitor (hereafter known as the *Vigileo* monitor). Edwards Lifesciences LLC intends to market the Edwards Dual Disposable Pressure Transducer (hereafter abbreviated as DDPT).

G. Predicate Device Identification

The *Vigileo* monitor and DDPT, the subjects of this notification, are substantially equivalent¹ to:

The term "substantial equivalence" as outlined in this premarket notification and the supporting information pertaining to equivalence are intended only to demonstrate equivalence to the predicate products for the purpose of obtaining clearance of the device pursuant to the Federal Food, Drug and Cosmetic Act. Reference to equivalence as outlined in this submission is in no way related to the term "equivalent" or similar terminology as outlined in patent laws.

510(k) No.	Device	How Is It a Predicate?	
Monitor			
K040287	Vigilance Continuous Cardiac Output/Oximetry/Continuous End Diastolic Volume monitor	The <i>Vigileo</i> monitor uses the same technology to measure oximetry as does the <i>Vigilance</i> monitor.	
K011238 Metracor RODA Monitoring System		Like the RODA System, the <i>Vigileo</i> monitor measures cardiac output via arterial pressure through a radial artery catheter connection without the need for calibration.	
DDPT:			
K925638	Phoenix Disposable Pressure Transducer (DPT)	The DDPT design consists of two Phoenix transducers glued together, with some other minor design changes to accommodate the DDPT's new intended use.	

H. Compliance with 513/514

No performance standards have been established under Section 514 of the Federal Food, Drug and Cosmetic Act.

II. Safety and Effectiveness Summary

A. 510(k) Summary

A 510(k) summary for the *Vigileo* monitor is provided in Appendix A in compliance with 21 CFR 807.92.

B. Class III Certification

Class III Certification is not applicable to this device.

III. Proposed Labeling and Advertising

A. Package Labels

The package labels for the *Vigileo* monitor and DDPT are provided in Appendix B.

B. Device Labels

The device labels for the *Vigileo* monitor and DDPT are provided in Appendix B.

C. Patient Labels

There are no patient labels for this device.

D. Statement of Intended Use

The *Vigileo* monitor is intended to measure arterial pressure cardiac output and oximetry. The monitor also calculates hemodynamic and oxygenation parameters.

The DDPT is intended to measure intravascular pressures. It is intended to transmit those pressure readings to both a standard blood pressure monitor and to the *Vigileo* monitor.

E. Instructions for Use

The instructions for use (Operator's Manual) of the *Vigileo* monitor and DDPT are provided in Appendix B.

F. Advertisement or Promotional Materials

No advertising has been developed for the proposed monitor.

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G. MRI Compatibility

Like the predicate devices, the *Vigileo* monitor does not directly contact the patient. In the event that a patient should require MRI, the monitor would be disconnected from the DDPT and the patient transported without it.

Therefore, MRI compatibility is not applicable.

IV. Device Description

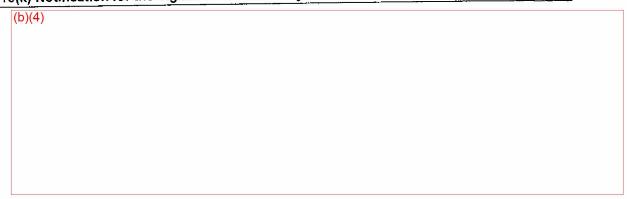
A. General Description, Components and Specifications

The Vigileo monitor is a microprocessor-based instrument that, when connected to a DDPT, continuously measures arterial pressure cardiac output (APCO). When connected to an Edwards oximetry catheter, the monitor measures oxygen saturation (oximetry). The monitor also calculates other derived parameters including cardiac index (CI), stroke volume (SV), stroke volume index (SVI), stroke volume variation (SVV), systemic vascular resistance (SVR), and systemic vascular resistance index (SVRI).

The *Vigileo* monitor is used with accessories that include a Patient APCO Cable (for cardiac output measurement), Optical Module (for oximetry) and various cables for receipt and transmission of data to/from other monitors. All of these accessories, except the APCO cable, are the same as those used with the predicate *Vigilance* monitor. The APCO cable has a proprietary connector that can only be used with the DDPT to transmit pressure signals to the *Vigileo* monitor. In addition, the Vigileo also has an available adapter plate that can be used to secure the monitor to a compatible stand, wall mount, 0 or countertop.

(b)(4)			

(b)(4)		



B. Diagrams, Engineering Drawings, Photographs

Drawings of the *Vigileo* monitor assembly and DDPT are provided in Appendix D.

C. Device Sample

Due to the nature of this product, a sample of the device is not provided with this document.

D. Service or Operator's Manual

The Operator's Manual for the Vigileo monitor is provided in Appendix B.

V. Comparative Information

A. Labeling

The labels for the *Vigileo* monitor are similar to those for the predicate *Vigilance* monitor. The shipping and product labels differ in the name of the product, model number and different patent numbers. The monitors have very different labels for the front- and rear-panel keypad buttons and connectors (described in the Operator's Manuals). The *Vigileo* front and back keypad/buttons are shown below. This is the *Vigileo* front panel:

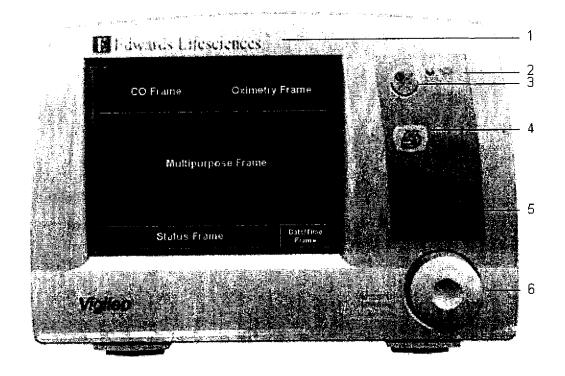
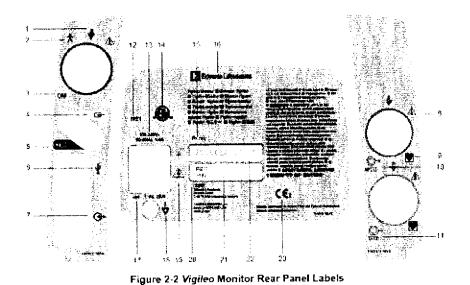


Figure Number	Symbol	Description
1	E Edwards Litesciences	Edwards Lifesciences logo
2	○-□	AC Label: When it is lit, it indicates the power cord is connected to an external AC power source.
3	%	Push Button: Power ON/OFF Power ON/ STANDBY push button, referred to in the text as ON/OFF.
4	3	Push Button: Start printer
5	•	Push Button: Silence alarm
6		Navigation knob .

This is the Vigileo back panel:



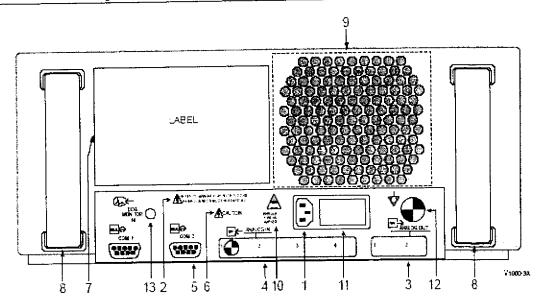
Page 11

Figure Number	Symbol	Description	
1	+	Connector Guide: Use to align connector cable to machine.	
2	*	Type B Equipment: Equipment protected against electric shock.	
3	OM	Connector Identification: Optical Module connection	
4	€	Connector: Analog output	
5	<u> </u>	Connector: Analog input	
6		Connector: USB port	
7	⊕ >	Connector: Serial COM Port	
8	\triangle	Caution: Read accompanying documents	
9		Type CF Equipment: Equipment is protected against electric shock, having an F-type isolated (floating) applied part. Intended for direct cardiac application.	
10	Ø→ APCO	Connector Identification; APCO connector	
11	©> TPTD	Connector Identification: Thermodilution connector (future option)	
12	IPX1	Degree of case waterproofing: Case provides protections against vertically falling water drops	
13	~	Alternating Current Voltage	
14	(II)	ETL Certification	
15	Rx only	Caution: Federal (USA) law restricts this device to use by, or on the order of, a physician.	
16	Fewards Lifesciences "	Edwards Lifesciences logo	



Figure Number	Symbol	Description	
17		Replacement fuse specification	
		Equipotential Grounding Post: The Equipotential Grounding Post may be used by facilities as required by their procedures.	
18		(Refer to service manual)	
19	A	Attention: Risk of electric shock	
20	EW)	Authorized representative in the European Community	
21	REF P.N:	Refurbished unit Part number Model designation	
	SN	Date of Manufacture	
22		Serial Number	
23	CC	CE mark: Certification to Annex II of EC Directive No. 93/422/EEC concerning medical devices.	

This is the front panel of the Vigilance monitor:



1. AC POWER INPUT

Use only the power cord supplied with the monitor. This connector accepts AC power ranging from 100 to 240 VAC, 50/60 Hz.

2. CAUTION

For safe operation, see Section 3.7 for instructions before connecting other devices.

3. ANALOG OUT

These 2 connectors provide the user with selectable analog signals for output to a chart recorder or other instruments via a 1/8 inch miniature phone plug.

4. ANALOG IN

These 4 connectors provide the instrument with input signals from other equipment via 1/8 inch miniature phone plugs.

COM1/COM2

These 2 connectors allow for connecting the instrument to a printer, or other clinical instrument, or other manufacturer's instruments, via 4-par RS-252 connectors.

6. CAUTION

To reduce the risk of electric shock, DO NOT remove back. Refer servicing to qualified service personnel.

7. INSTRUMENT SERIAL NUMBER

Numerical identification required when contacting Edwards Technical Support.

8. HANDLES

The plastic handles provide convenient portability for the instrument.

9. FAN OUTPUT

Opening allows for air output from the instrument fan.

10. CAUTION

Replace fuse as marked.

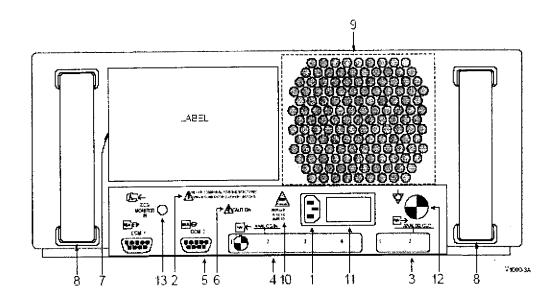
11, FUSE HOLDER

12. EQUIPOTENTIALITY GROUND

13. ECG MONITOR IN

This connector provides the instrument with the ECG input signal from a bedside monitor via 1/4 inch miniature phone plug.

This is the back panel of the *Vigilance* monitor:



1. AC POWER INPUT

Use only the power cord supplied with the monitor. This connector accepts AC power ranging from 100 to 240 VAC, 50/60 Hz.

. 2. CAUTION

For safe operation, see Section 3.7 for instructions before connecting other devices.

ANALOG OUT

These 2 connectors provide the user with selectable analog signals for output to a chart recorder or other instruments via a 1/8 inch miniature phone plug.

4. ANALOG IN

These 4 connectors provide the instrument with input signals from other equipment via 1/8 inch miniature phone plugs.

COM1/COM2

These 2 connectors allow for continuing the instrument to a printer, or other clinical instrument, or other manufacturer's instruments, via 9-pin RS-232 connectors.

CAUTION

To reduce the risk of electric shock, DO NOT remove back. Refer servicing to qualified service personnel.

· 7. INSTRUMENT SERIAL NUMBER Numerical identification required when

contacting Edwards Technical Support.

8. HANDLES

The plastic handles provide convenient portability for the instrument.

FAN OUTPUT

Opening allows for air output from the instrument fan.

10. CAUTION

Replace fuse as marked.

11. FUSE HOLDER

12. EQUIPOTENTIALITY GROUND

13. ECG MONITOR IN

This connector provides the instrument with the ECG input signal from a bedside monitor via 1/4 inch miniature phone plug.

The labels for the DDPT are similar to those for the predicate DPT. The shipping and product labels differ in the name of the product, model number, and international symbols.

The Operator's Manual for the *Vigileo* monitor provides comparable information for the proposed device as the predicate *Vigilance's* Operator's Manual. The main differences between the two Operator's Manuals are listed below.

- The *Vigileo* monitor does not measure as many parameters as the predicate device, so the *Vigileo's* Operator's Manual is shorter than the predicate's.
- Because the *Vigileo* monitor measures cardiac output in a much different fashion than the predicate *Vigilance*, the Operator's Manual has been modified accordingly.
- The format has been changed and the instructions have been modified to correspond with the *Vigileo's* graphical user's interface (GUI).

The DFU for the DDPT is almost identical to the DFU for the predicate DPT. Changes were made to the new DFU to accommodate the design changes between the two devices. (The most significant and obvious design change being the fact that the DDPT is two DPTs glued together). The design changes were made to accomplish the DDPT's new intended use – to be used in conjunction with the *Vigileo* monitor to measure cardiac output.

The labeling for the proposed *Vigileo* monitor and DDPT is provided in Appendix B. The labeling for the predicate devices is provided in Appendix C.

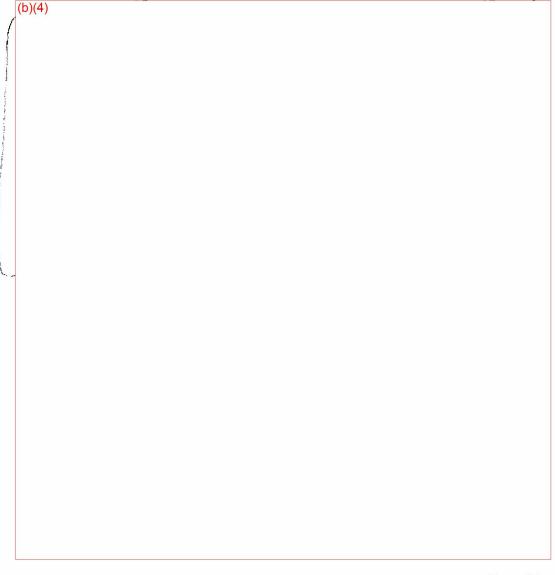
B. Intended Use

The proposed *Vigileo* monitor, like the predicate *Vigilance* monitor, is intended to measure cardiac output and oximetry. The *Vigileo* monitor, however, measures cardiac output via an arterial pressure waveform, while the *Vigilance* monitor uses the thermodilution method to determine cardiac output. Like the predicate *Vigilance* monitor, this system also calculates hemodynamic and oxygenation parameters.

The proposed DDPT, like the predicate DPT, is intended to measure intravascular pressures. Unlike the predicate DPT, it is also intended to be used in conjunction with the *Vigileo* monitor to measure cardiac output.

C. Physical Characteristics

The *Vigileo* monitor differs from the *Vigilance* monitor in its physical specifications and configuration (see table below and Section V.A above). While the hardware for the two devices differs, the proposed device has comparable performance specifications to the predicate *Vigilance* device. In addition, like the predicate *Vigilance* device, the *Vigileo* monitor has been shown to meet UL and CSA as well as EMC requirements.



















D. Anatomical Sites

The *Vigileo* monitor is connected to the DDPT using an electrical cable. The DDPT is attached to a radial or femoral artery catheter and a pressurized saline bag using a peripheral tubing line. For oximetry readings, the *Vigileo* monitor is attached, via an optical module, to an oximetry catheter which is placed within the patient's circulatory system. For cardiac output measurements, the predicate *Vigilance* monitor is attached to a catheter that is placed in the pulmonary artery for hemodynamic measurements. For oximetry readings, the *Vigilance* monitor is attached, via an optical module, to an oximetry catheter which is placed within the patient's circulatory system. The predicate RODA device is connected to an arterial catheter.

E. Target Population

The target population for this product, as with the predicate devices, includes patients who require hemodynamic monitoring.

F. Performance Testing

Bench testing was performed to verify that the *Vigileo* monitor meets the same specifications as the predicate *Vigilance* device. The cardiac output and oximetry parameters were evaluated.

The test results	(b)(4)

a. Cardiac Output Testing

1) DDPT Recognition and Cable Test

Method: (b)(4)

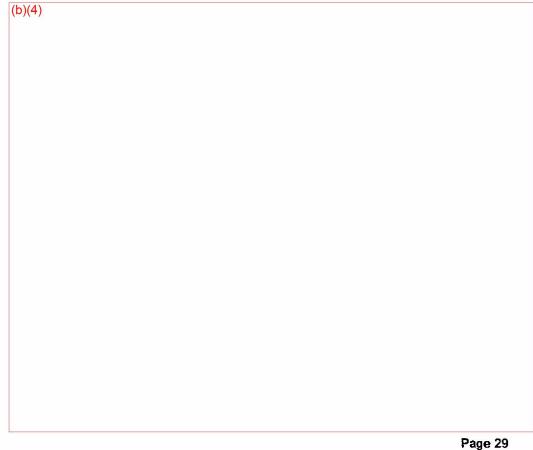
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	Results:	
	(b)(4)	The data
	demonstrate that the Vigileo monitor displayed and record	ed the correct
	pressure values, within the specified tolerance limits, at a	level of 95%
	confidence for 99% of the population.	
(b)(4)		
	3) APCO Algorithm Repeatability Test	
	Method:	
	(b)(4)	

Results:	
(b)(4)	
(b)(4)	Therefore, the APCO algorithm meets its specification
(b)(4)	as provided in the
Operator's ma	anual.
4) APCO Al	Igorithm Verification Test

Method:



0)(4)				
/(- /				
Reculter				
Results:				
(b)(4)				
	testing shows that	the computation	s of the <i>Vigiled</i>	monitor
(b)(4)	testing shows that	the computation	s of the <i>Vigiled</i>	monitor

h	Oximetry Testing
	Oximetry testing was conducted to evaluate the oximetry function of the
	Vigileo monitor. (b)(4)
	b)(4)
(b)(4)
Ĺ	
	1) Oximetry Precision
	Method:
(1	0)(4)

Action for the angular	
(b)(4)	
Results:	
(b)(4)	
(-)(-)	
(b)(4)	precision was within the specification of ±2 % as
	monitor Operator's Manual.
(b)(4)	

c.	DDPT Testing
	(b)(4)
	1) Leak Test
((b)(4)
	acceptance criterion was mee.
	2) Avial Dull between the Transducers
	2) Axial Pull between the Transducers
	(b)(4)

(b)(4)			this acceptanc
criterion v	vas met.		
b)(4)			
2) D U.C	the street hat was the	Transducers at	nd Rackplate
	trength between the	Transducers ar	и Васкріате
(b)(4)			
(b)(4)	acceptance (criterion was n	net.
(b)(4)			
	bbling/Frequency Re	sponse	
(b)(4)			

	(b)(4)						
	(b)(4)			/b)			
	(b)(4)			(b) (4) ac	ceptance cr	iterion was	s met.
)							
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acceptance criterion was met.

(b)(4)		
(७)(५)		
	6) Metered Flow Rate	
		•
•	(b)(4)	
	(I-VA)	
	(b)(4)	acceptance criterion was met.
	(b)(4)	

b)(4)			
(b)(4)			acceptance criterion was me
)(4)			
9) Capa	acitance Value Veri:	fication	
b)(4)	acceptance criter	rion was met.	
)(4)			

Conclusion:

The results of the bench testing demonstrate that the performance of the *Vigileo* monitor meets the requirements for the monitor functions; these oximetry requirements being the same as those for the predicate *Vigilance*





monitor, thus demonstrating equivalence with the predicate device. The testing also demonstrated that the APCO performance met the reproducibility specification. These results also demonstrate that the performance of the DDPT meets the requirements for transducer functions, these requirements being the same for the DDPT as they are for the predicate DPT.

~	4 . 1	THE STATE OF THE S
2.	Animal	Lectino
4.	Allimat	LUSHIIE

No animal testing was conducted for this submission.

- 3. Clinical Testing
- a. Summary

(b)(4)	
(b)(4)	
(b)(4)	The primary objective of this study was to collect data for
bench asse	ssment to evaluate bias and precision of the APCO algorithm
when comp	pared to the well-accepted ICO method.

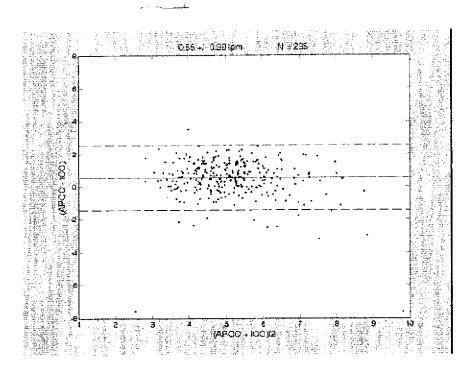
(b)(4)			

(4)			
•			• •
Results and Cond	clusions		

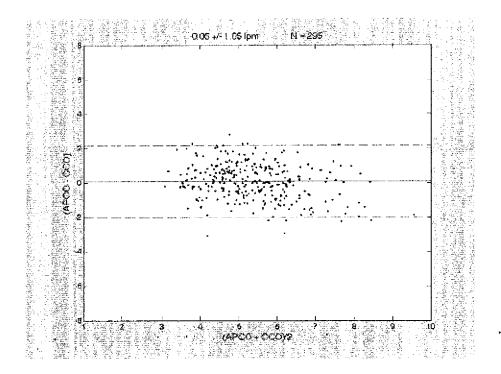
b.

b)(4)	

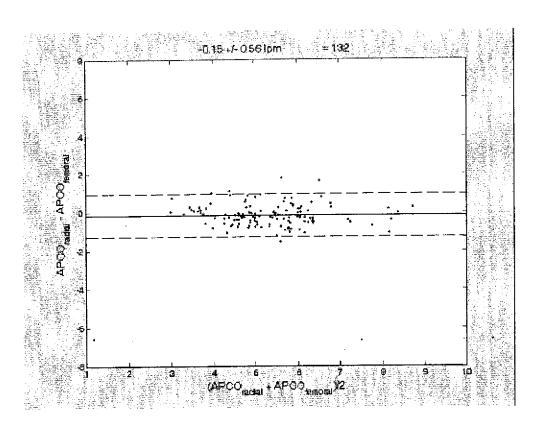
This is the Bland-Altman plot of the differences between APCO and ICO. The mean bias was 0.55 l/min (indicated by the solid line) and the precision was 0.98 l/min. The plot shows that variations in CO are tracked similarly by APCO and ICO.



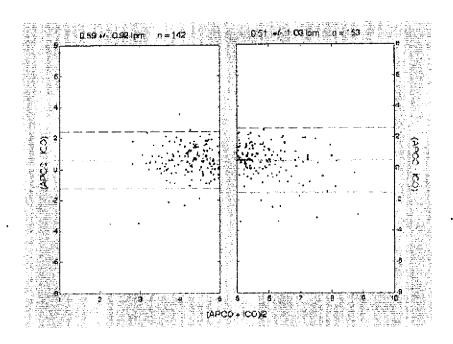
This plot shows the results of the analysis comparing APCO to CCO. The mean bias was 0.06 l/min and the precision was 1.05 l/min. As in the table above, this plot shows that variations in CO are tracked similarly by APCO and CCO.



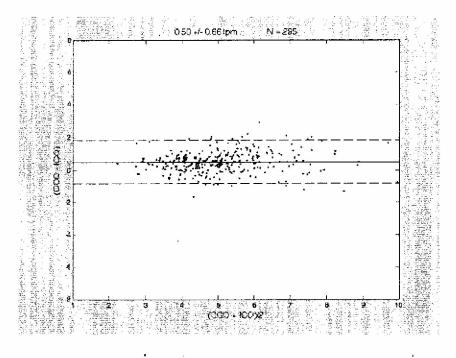
A Bland-Altman analysis on 21 subjects with 132 measurement pairs of radial APCO vs. femoral APCO was conducted and displayed below. The mean bias was -0.15 l/min and the precision was 0.56 l/min.



In order to assess the precision and bias of the APCO algorithm in high (≥5.0 l/min) and low (< 5.0 l/min) cardiac output when compared to ICO, the Bland-Altman plot below was generated. The plot on the left displays the values for low cardiac output (142 samples, mean bias 0.59 l/min, precision of 0.92 l/min). The plot on the right displays the values for high cardiac output (153 samples, mean bias 0.51 l/min, precision of 1.03 l/min).



This plot shows the results of the analysis comparing CCO to ICO. The mean bias was 0.50 l/min and the precision was 0.66 l/min.



(b)(4)

(b)(4)

The data from the comparisons between APCO and currently accepted CO techniques (ICO and CCO) show that APCO has clinically acceptable accuracy and precision results. Likewise, the comparisons between radial and femoral APCO measurements shows that the APCO algorithm works well in either access site. Based on this, either arterial monitoring line may be used for CO measurement with the APCO algorithm. The comparisons between high/low APCO vs. high/low ICO values show

negligible difference in the bias and precision in the analyses between CO ranges.

G. Safety Characteristics

Testing has been conducted on the *Vigileo* monitor to demonstrate compliance with the safety standards of Underwriter's Laboratories (UL) and Canadian Standards Association (CSA). In addition, the monitor has been demonstrated to meet the requirements of EN60601-1:1990, A1:1993, A2:1995 for safety of medical electrical equipment; EN60601-1-2:2001 for electromagnetic compatibility; EN60601-1-1: 2000 for safety of electrical medical systems and EN60601-2-49: 2001 for safety of multifunction monitoring equipment. The safety characteristics for the proposed monitor are equivalent to that of the predicate *Vigilance* device.















IX. Specific Standards and Guidances

A. List of Applicable Standards and Guidances

The following FDA Guidance document was used in the preparation of this premarket notification.

 Guidance for FDA Reviewers and Industry, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Issued May 29, 1998.

In addition, the *Vigileo* monitor complies with the following standards:

- EN60601-1:1990, A1:1993, A2:1995, Medical Electrical Equipment, Part 1: General requirements for safety
- EN60601-1-1:2000, 2nd Edition, Medical Electrical Equipment, Part 1: General requirements for safety – Collateral Standard Safety Requirements for Medical Electrical Systems
- EN60601-1-2:2001, Medical Electrical Equipment, Part 1-2: General requirements for safety Collateral Standard. Electromagnetic Compatibility. Requirements and Tests)
- EN60601-2-49:2001, Medical Electrical Equipment, Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment
- UL 60601-1-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
- CAN/CSA No. 601.1S1-94 (IEC601, Amendment 1:1991) Supplement No 1-94 to CAN/CSA C22.2 No. 601.1-M90, Electromedical Equipment, Canadian Standards Association

The DDPT complies with the following standards:

- ANSI/AAMI BP 22, Blood Pressure Transducers, 2nd edition, 1994.
- FDA General Program Memorandum No. G95-1: Required Biocompatibility Training and Toxicological Profiles for Evaluation of Medical Devices.
- ISO 10993-1: 1994 Biological evaluation of medical devices Part 1: Selection of tests.

B. Kit Certification

Neither the *Vigileo* monitor nor the DDPT are part of a kit, therefore this section is not applicable.

X. Bibliography

Copies of these articles are provided in Appendix P.

- Bland JM, Altman DG. Statistical Methods for Assessing Agreement Between Two Methods of Clinical Measurement. *Lancet* 1986; 1: 307-10.
- Gould KA,, Hartigan C, Keane, SF "Cardiac Output Measurement Techniques (Invasive)" in AACCN Procedure Manual for Critical Care, 4th edition Debra J. Lynn-McHale and Karen K Carlson eds. (W.B. Saunders Co: New York, 2001).

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Appendix A

510(k) Summary

510(k) Summary

Submitter:

Edwards Lifesciences LLC

One Edwards Way

Irvine, CA 92614-5686

Contact Person:

Jason Smith, Senior Regulatory Affairs Specialist

Date Prepared:

November 4, 2004

Trade names:

Vigileo Arterial Pressure Cardiac Output/Oximetry

(APCO/Oximetry) Monitor

Edwards Dual Disposable Pressure Transducer (DDPT)

Classification

Monitor:

Name:

Single-Function, Preprogrammed Diagnostic Computer

(21 CFR 870.1435)

Transducer:

Extravascular Blood Pressure Transducer (21 CFR

870.2850)

Predicate

Monitor:

Devices:

Vigilance Continuous Cardiac Output/Oximetry/Continuous

End Diastolic Volume (CCO/SvO₂/CEDV) Monitor

Metracor RODA Monitoring System

Transducer:

Phoenix Disposable Pressure Transducer

Device

Description:

The *Vigileo* APCO/Oximetry monitor is a microprocessor-based instrument which, when connected to a DDPT,

continuously measures arterial pressure cardiac output

(APCO). When connected to an Edwards oximetry catheter, the monitor measures oxygen saturation (oximetry). The monitor also calculates other derived parameters including cardiac index, stroke volume, stroke volume index, stroke volume variation, system vascular resistance, and systemic

vascular resistance index.

Intended Use:

The Vigileo APCO/Oximetry monitor is intended to measure arterial pressure cardiac output and oximetry. The monitor

also calculates hemodynamic and oxygenation parameters.

The DDPT is intended to measure intravascular pressures. It is intended to transmit those pressure readings to both a standard blood pressure monitor and to the *Vigileo* monitor.

Comparative Analysis:

Both the Vigileo APCO/Oximetry monitor and the DDPT

have been demonstrated to be as safe and effective as the

predicate devices for their intended uses.

Functional/Safety

Testing:

Both the Vigileo APCO/Oximetry Monitor and the DDPT

have successfully undergone functional testing as well as

electrical safety testing. They have been shown to be

equivalent to the predicate devices.

Conclusion:

The Vigileo APCO/Oximetry Monitor and DDPT are

substantially equivalent to the predicate devices.

Jason Smith

Senior Regulatory Affairs Specialist

Edwards Lifesciences LLC

A 003

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Appendix B

Proposed Labeling

CONFIDENTIAL

Vigileo Monitor Shipping Label



В

Edwards Lifesciences

Ony.雷北

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Edwards Liteschences, the stylized Ellogo and Vigilies are trademarks of Edwards Liteschences Corporation.

Edwarde Lifecciences LLC Invins, CA 926145695 USA Made in USA

EC REP

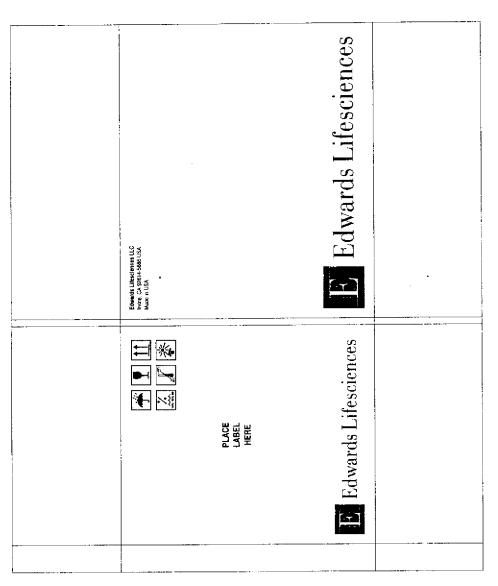
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11-60199 REV 00

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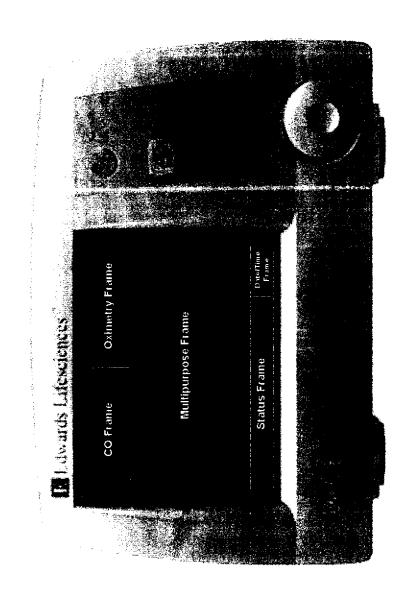
Vigileo Monitor Shipping Box

100



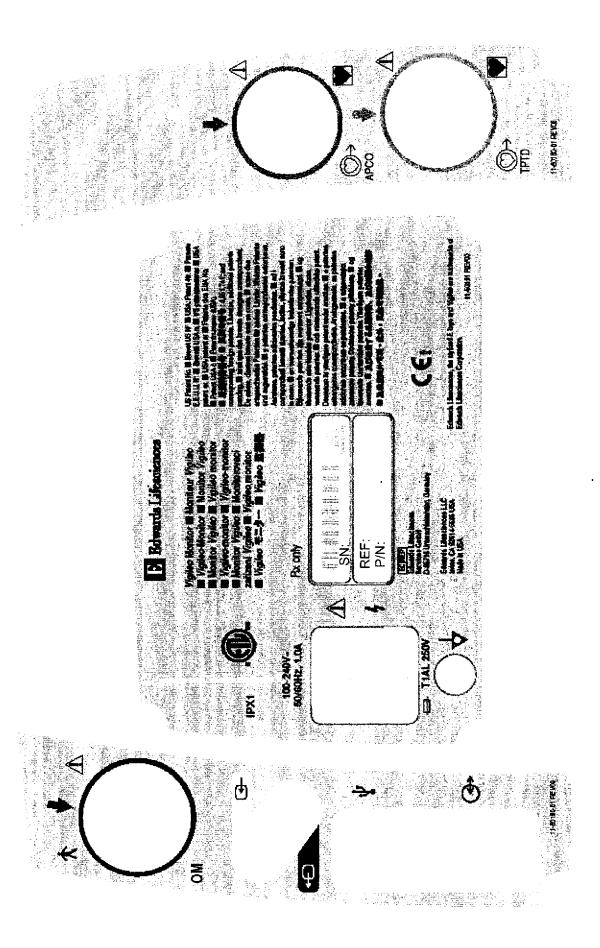
1 of 2 Right Side Panel

Vigileo Monitor Unit Label



B 007

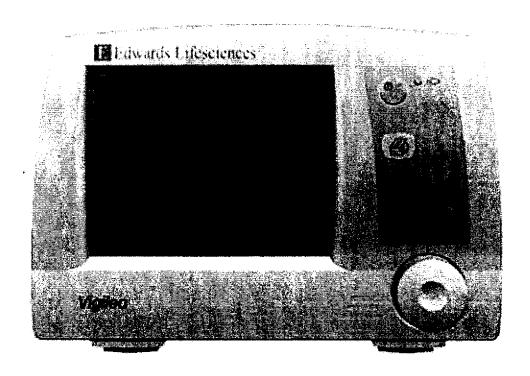
Vigileo Monitor Rear Panel Labels



Vigileo Monitor Operator's Manual

Vigileo Monitor

Arterial Pressure Cardiac Output/Oximetry (APCO/SvO₂) Monitor





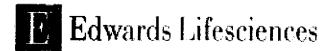
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards Lifesciences, the stylized E logo, Vigiteo and Edwards are trademarks of Edwards Lifesciences Corporation; Co-Set and Vigiteo are registered in the United States patent and trademark office. Flexport and PCMS are trademarks of SpaceLabs, Inc.

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Edwards Lifesciences S.A. • Ch. du Glapin 6 • 1162 St-Prex • Switzerland • 41.21.823.4300

Edwards Lifesciences Japan • 2-8 Rokubancho • Chiyoda-ku, Tokyo 102-0085 • Japan • 81.3.5213.5700

Rev. 001

Edwards Lifesciences

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Preface

Edwards Lifesciences Vigileo Monitor Operator's Manual

(Preliminary) 2004

Because of continuing product improvement, prices and specifications are subject to change without notice. Changes to this manual, either in response to user input or to continuing product improvements, are accomplished through reissue. If, in the normal use of this manual, errors, omissions, or incorrect data are noted, please contact Edwards Technical Support or your local Edwards representative.

Issued by Edwards Lifesciences LLC

One Edwards Way Irvine, CA 92614-5686

Made in USA

Patents This product is manufactured and sold under one or more of the

following US patent(s): US Patent No. 4,507,974; 4,651,741; 5,146,414; 5,305,760; 5,553,622; 5,634,470; 5,701,908; 5,755,670; 5,588,438; 5,687,733; 5,720,293; 6,045,512; 6,371,923; and

corresponding foreign patents. Additional patents pending.

Trademarks Edwards Lifesciences, the stylized E logo, Vigilance, Edwards, and

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office. Flexport and PCMS are trademarks of SpaceLabs, Inc.

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Printed in the United States of America.

2004







Edwards Lifesciences Services GmbH

Edisonstr. 6

D-85716 Unterschleissheim, Germany

Caution:

Federal (USA) law restricts this device to sale by or on the order of a

physician.

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Edwards Lifesciences

Rev. 001

Using This Manual

The *Vigileo* monitor operator's manual comprises 12 chapters and eight Appendices. Each chapter provides the information relevant to a specified monitoring function or input/output processing. Although this results in some duplication between chapters, the manual design minimizes the look-up time for setup and operation of any monitoring feature.

Chapter	Description
1	Vigileo Operational Environment: Includes an overview of the Vigileo monitor modes, functions and interfaces between the monitor accessories.
2	Safety and Symbols: Includes definitions of WARNINGS, CAUTIONS, and NOTES that are found in the manual, as well as illustrations of labels found on surfaces of the monitor.
3	Quick-Start Guide to Operation: Provides experienced clinicians and users of bedside monitors an immediate use of the monitor.
4	Unpacking, Installation and Initial Setup: Provides information about the different accessories and options that may be used with the <i>Vigileo</i> monitor. Includes a description of the Power-On Self Test performance check of critical hardware components.
5	Monitor Display, Controls, Alarms and Indicators: Provides details of the monitor display screen layouts, keypad buttons, navigation knob, front and rear panel labels, how to customize the displays, and instructions for disabling, enabling and silencing alarms.
6	APCO Monitoring: Provides instructions for operating the monitor when using the Arterial Pressure Cardiac Output (APCO) mode. Includes instrument setup, screen configurations, error messages. Also provides a guide to operator troubleshooting when in the CCO mode.
7	Oximetry: Describes procedures for calibration and operation of oximetry (oxygen saturation) measurement in the Vigileo monitor.
8	Monitor Status and Configuration: Describes screen and port configurations and provides information on setting up monitor features.
9	Date and Time : Describes the Date and Time Frame and provides instructions for setting the date and time as well as restoring defaults.
10	Data Display: Describes the various monitor frames monitor display screen layouts.
11	Reports: A grey scale bit map of the screen can be sent to a printer via the USB Port.
12	Troubleshooting : Lists faults and alerts and their appropriate references for suggested operator action.

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Chapter 1 *Vigileo* Operational Environment

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1.1 Indications for Use

The Vigileo monitor allows the clinician to continuously measure hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption.

1.2 Overview

The Vigileo monitor is a minimally invasive monitoring platform that measures APCO (arterial pressure cardiac output), venous oxygen saturation (both central - ScvO₂ and mixed - SvO₂), and SV (stroke volume), as well as derived continuous SVR when interfaced with the appropriate bedside monitors. Calibration for ScvO₂/SvO₂ is required, whereas APCO has AutoKal or manual calibration options. This monitor, in conjunction with other bedside monitors and clinical assessment, assists in assessing the patient's status, and determining the need of and adequacy of therapy in the management of critically ill patients.

The *Vigileo* monitor is suitable for use in the patient environment as indicated in IEC 60601-1-1.

WARNING Use of the Vigileo monitor is restricted to one patient at a time.	
WARNING	
Read this manual carefully before attempting to use the Edwards Lifesciences Vigileo monitor.	•

1.2.1 Arterial Pressure Cardiac Output (APCO)

The *Vigileo* monitor uses the arterial pressure waveform to continuously measure cardiac output. The variability of the pulse pressure is measured. This variability, when scaled with the appropriate vascular compliance measure, is equal to the stroke volume. The cardiac output is computed by multiplying the measured stroke volume by an estimate of pulse rate determined from the pressure waveform.

1.2.2 Oximetry - Central Venous Oxygen Saturation (ScvO₂)/ Mixed Venous Oxygen Saturation (SvO₂)

The Vigileo monitor measures both central venous oxygen saturation ($ScvO_2$) and mixed venous oxygen saturation (SvO_2) using a spectrophotometric technique. It uses light-emitting diodes (LEDs) to transmit light in the red and infrared spectra through an optical fiber in a central venous catheter to the blood. The light is reflected back from the venous blood through a separate optical fiber in the catheter to an optical module. The amount of light reflected is primarily dependent on the color, which is due to the amount of oxygen bound to the hemoglobin and the amount of red blood cells present. The reflected light is electrically measured by the monitor and analyzed to determine $ScvO_2/SvO_2$ by detecting color changes in the red blood cells.

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1.3 Vigileo Monitor Operator's Manual

The *Vigileo* monitor Operator's Manual is intended for use with the Edwards Lifesciences *Vigileo* monitor by trained critical care clinicians, nurses, and physicians in any hospital environment where critical care is administered. These include, for example, emergency rooms, intensive care units, cath labs, recovery rooms, and burn units.



WARNING

Do not use a defibrillator while the monitor is connected to the patient,

This manual provides the operator with setup and operating instructions, device interface procedures, and limitations. It also provides instructions for all user configurations and describes the operational environment in which the *Vigileo* monitor can be installed. This includes connections and communications to devices and monitors within that environment.

1.4 Vigileo Monitor Basic System Components

Figure 1-1 identifies monitor connection points.

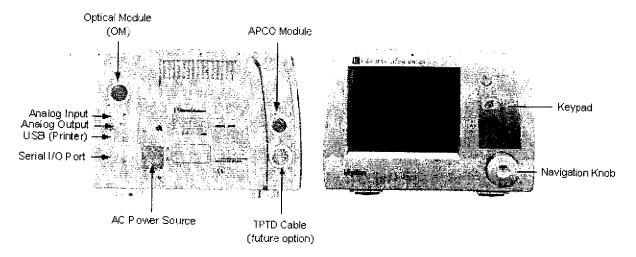


Figure 1-1 Vigileo Basic System Components

1.5 Acronyms and Abbreviations

The following acronyms and abbreviations are used in this manual.

Table 1-1 Acronyms, Abbreviations and Definitions

Abbreviation	Definition	Abbreviation	Definition
APCO	Arterial Pressure Cardiac Output	NVRAM	Non Volatile Random Access Memory
AutoKal	Automatic calibration of the APCO	PAC	Pulmonary Artery Catheter
BP	Blood Pressure	POST	Power on self test
BSA	Body Surface Area	PR	Pulse Rate
CI	Cardiac Index	ScvO ₂	Central Venous Oxygen Saturation
c o	Cardiac Output	SQI	Signal quality Index
CVC	Central Venous Catheter	sv	Stroke Volume
CVP	Central Venous Pressure	SVI	Stroke Volume Index
DPT	Disposable Pressure Transducer	SvO ₂	Mixed Venous Oxygen Saturation
EO	Ethylene Oxide	SVR	Systemic Vascular Resistance
Hct	Total Hematocrit	SVRI	Systemic Vascular Resistance Index
HGB	Total Hemoglobin	SVV	Stroke Volume Variation

1.6 Symbols and Icons

The text includes a number of symbols that appear as markings on the *Vigileo* monitor front and rear case panels. In addition, the safety warnings, cautions and notes in the manual are printed with standard symbols/icons. See Chapter 2: Safety and Symbols on page 2-1 for a list and description of the panel symbols and icons. In addition, a complete list of all symbols used for the *Vigileo* monitor labels is provided in Chapter 2. Additional symbols that appear on the screen are described in the appropriate chapter.

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2.1 Overview

This chapter describes the symbols that appear within the manual or in the product labels, including those used to identify a warning, caution, or note. A list of all warnings and cautions used in this manual is provided later in the chapter.

Chapter 2 also includes a listing of relevant standards to which the *Vigileo* monitor complies.

2.2 Safety Identifying Symbols

The terms warnings, cautions, and notes are graphically identified and have specific meanings as used in this manual..



WARNING

Advises against certain actions or situations that could result in personal injury or death.



CAUTION

Advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.



NOTE

Draws attention to useful information regarding a function or procedure.

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2.2.1 Warnings

The following warnings are used in the *Vigileo* monitor Operator's Manual. They are introduced in the manual where relevant to the function or procedure being described.

Table 2-1 Warnings

Operation	al Safety Requirements
	WARNING
	Read this manual carefully before attempting to use the Edwards Lifesciences Vigileo monitor.
	(Chapter 1)
	WARNING
	Use of the Vigileo monitor is restricted to one patient at a time. (Chapter 1)
	WARNING
	Improper use of the Vigileo monitor could present a hazard to the patient. Carefully read the "Warnings" section of this manual (in Chapter 2: Safety and Symbols) before using the instrument. (Chapter 3)
	WARNING
	The Vigileo monitor is intended for use only as an adjunct in patient assessment. This instrument must be used in conjunction with patient clinical signs and symptoms. Read this operator's manual carefully before attempting to use the Edwards Lifesciences Vigileo monitor. (Chapter 3, 4)
	WARNING
	Explosion Hazard! Do not use the monitor in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide. (Chapter 4)
A	WARNING
	The analog and digital communication ports of the monitor share a common ground that is isolated from the catheter interface electronics. When connecting multiple devices to the <i>Vigileo</i> monitor, all devices should be provided with isolated power to avoid compromising the electrical isolation of any of the connected devices. (Chapter 4)
	WARNING
	Make sure the Vigileo monitor is securely mounted, and that all cords and accessory cables are appropriately arranged to minimize the risk of damage to patients, users or the equipment. (Chapter 4)
A	WARNING
	To prevent injury, do not use a damaged <i>Vigileo</i> monitor or accessory. (Chapter 4)

Table 2-1 Warnings

A	WARNING
	Do not use a damaged catheter or one with exposed electrical contacts.
	(Chapters 4, 7)
	WARNING
	Do not use any catheter that has been used previously.
	(Chapter 4)
	WARNING
	Do not use extension cords or multiple socket devices to connect power to the monitor. Do not use any other detachable power cords other than the power cord provided. (Chapter 4)
	WARNING
	Do not use the <i>Vigileo</i> monitor as a pulse rate or blood pressure monitor. (Chapter 6)
•	WARNING
	Do not turn off the alarms in situations in which patient safety could be compromised.
	(Chapters 6, 7)
	WARNING
	The Vigileo monitor contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages. (Appendix E)
	WARNING
	Shock or fire hazard! Do not immerse the Vigileo monitor or cables in any liquid solution. Do not allow any fluids to enter the instrument. (Appendix E)
	WARNING
	The Vigileo monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Vigileo monitor should be observed to verify normal operation in the configuration in which it is used.
	(Appendix F)
	WARNING
	There are minimum amplitudes for the <i>Vigileo</i> monitor to measure physiological signals. Operation of the equipment below the minimum amplitudes may cause inaccurate results.
	(Appendix F)

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Table 2-1 Warnings

Accessor	es Usage Requirements
	WARNING
	Do not use a defibrillator while the monitor is connected to the patient.
	(Chapters 1, 4, 6)
	WARNING
	Do not use any Disposable Pressure Transducer that has been used previously. (Chapter 4)
A	WARNING
	Refer to the directions for use provided with each catheter for specific instructions on catheter placement and use, and for relevant WARNINGS, CAUTIONS and NOTES. (Chapter 4)
A	WARNING
	Use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the <i>Vigileo</i> monitor. (Chapter 4, Appendix F)
A	WARNING
	Make sure all equipment and accessories connected to the monitor are properly grounded. (Chapter 4)
	WARNING
	Refer to the directions provided with each accessory for specific instructions on accessory placement and use, and for relevant WARNINGS, CAUTIONS, and SPECIFICATIONS.
	(Chapters 4, 7)
	WARNING
	Refer to the directions for use provided with each Disposable Pressure Transducer for specific instructions on Disposable Pressure Transducer placement and use, and for relevant WARNINGS, CAUTIONS and NOTES.
	(Chapter 4)
	WARNING
	Do not use a damaged Disposable Pressure Transducer or one with exposed electrical contacts.
	(Chapter 4)
	WARNING All IEC/EN 60950 equipment, including printers, must be positioned no closer than 1.5 meters to the patient's bed.
	Printers must have an ITE Class II power supply. (Chapter 11)

Table 2-1 Warnings



WARNING

Connect only accessories that have been qualified as part of the $\it Vigileo$ monitoring system.

(Appendix A)

Monitor Maintenance



WARNING

The *Vigileo* monitor contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages. (Appendix E)

2.2.2 Cautions

The following cautions are used in the *Vigileo* monitor operator's manual. They are introduced in the manual where relevant to the function or procedure being described.

Table 2-2 Cautions

Monitor Opera	tion
\wedge	CAUTION
	Inaccurate APCO cardiac output measurements can be caused by factors such as: • 'Improperly zeroed and/or leveled transducer • Over or under damped pressure lines • Excessive variations in blood pressure. Some examples that cause BP variations include, but are not limited to: * Post cardiopulmonary bypass surgery status * Intra-aortic balloon pumps • Any clinical situation where the arterial pressure is deemed inaccurate
	Excessive patient movement Electrocautery or electrosurgical unit interference (Chapter 3)
\wedge	CAUTION
	The only way to remove powe. Somethe monitor is to unplug the power cord from its power source. (Chapters 3, 4)
\wedge	CAUTION
\triangle	Performing an <i>in vitro</i> calibration after the catheter has been inserted into the patient will yield erroneous calibration. (Chapters 3, 7)
\wedge	CAUTION
	The catheter and the calibration cup must be dry for an accurate in vitro calibration. Flush the catheter lumen only after the in vitro calibration has been completed. (Chapters 3, 7)

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Table 2-2 Cautions

	CAUTION
	Do not expose the <i>Vigileo</i> monitor to extreme temperatures. (Chapter 4)
\triangle	When connecting the <i>Vigileo</i> monitor to any external device, refer to the device's instruction manual for complete instructions. Verify proper operation of the system before clinical use. (Chapter 4)
	CAUTION
	Prior to catheter insertion, refer to directions for use provided with each catheter for complete description, instructions, warnings, cautions and specifications. (Chapter 4)
\wedge	CAUTION
	Do not use the monitor as a hand-held device. (Chapter 4)
\wedge	CAUTION
	Use Edwards-compatible accessories only to avoid damage to the monitor and to ensure accuracy of patient information. (Chapter 4)
^	CAUTION
	Prior to connection of the pressure transducer, refer to directions for use provided with each Disposable Pressure Transducer for complete description, instructions, warnings, cautions and specifications. (Chapter 4)
\wedge	CAUTION
\triangle	Always grasp the connector, not the cable, when connecting or disconnecting the cable. (Chapter 6)
Λ	CAUTION
\triangle	Do not twist or bend the connectors. (Chapter 6)
\wedge	CAUTION
	Do not disconnect the optical module while calibration and patient data are being transferred from the <i>Vigileo</i> monitor. (Chapters 7, 10)

Ta	bl	e 2	-2	Ca	ruti	io	ns

	Table 2-2 Cautions
	CAUTION
	The accuracy of continuous SVR depends upon the quality and accuracy of the CVP data transmitted from the external monitors. Since CVP analog signal quality from the external monitor cannot be validated by the <i>Vigileo</i> Monitor, actual values and the values (including all derived parameters) displayed by the monitor may not be consistent. Refer to the external input device operator's manual for detailed information regarding accuracy, calibration, and other variables which may impact the analog output signal from the external monitor. (Chapter 8)
	CAUTION
	In order to avoid data corruption, always disconnect the patient cable and optical module from the <i>Vigileo</i> monitor before using a defibrillator. (Chapter 10)
Monitor Mainte	nance
\wedge	CAUTION
	Do not obstruct the Vigileo monitor ventilation openings.
	(Chapter 4)
\wedge	CAUTION
	Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing. (Appendix E)
	CAUTION
	You can lightly wipe the top, bottom and front surfaces with the cloth, but the monitor screen and its accessories MUST NOT have liquid poured or sprayed directly on them. (Appendix E)
^	CAUTION
	DO NOT:
	 allow any liquid to come in contact with the power connector, fuse holder, or switches allow any liquid to penetrate connectors or openings in the case. clean the monitor's rear panel If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the monitor. Disconnect power immediately and call your local Edwards Representative. (Appendix E)
\wedge	CAUTION
	DO NOT attempt to clean the rear panel of the monitor. (Appendix E)
\wedge	CAUTION
\triangle	Do not steam, radiate, or EO sterilize.
į	Do not immerse.
	(Appendix E)

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	CAUTION
	If any electrolytic solution is introduced into the transducer connector of the cable while it is connected to the monitor and the monitor is turned on, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts.
	(Appendix E)
\wedge	CAUTION
	Do not immerse the connector in detergent, isopropyl alcohol, or glutaral-dehyde.
	(Appendix E)
\wedge	CAUTION
	Do not immerse the connector in these cleaning agents.
	(Appendix E)
Λ	CAUTION
	Do not use a hot air gun to dry the connector.
	(Appendix E)

2.3 Monitor Case Symbols

This section illustrates and describes all symbols included on the surfaces of the *Vigileo* monitor. Their locations are shown in Figure 2-1 (front panel) and Figure 2-2 (rear panel).



NOTE

Additional symbols that appear on the monitor screen are described in the appropriate chapters.

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2.3.1 Monitor Front

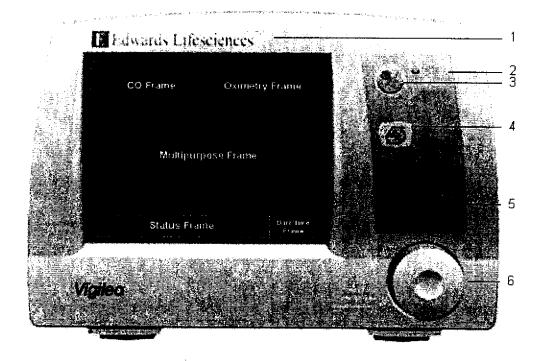


Figure 2-1 Vigileo Monitor Front Panel Symbols

Table 2-3 Monitor Front Symbols and Connectors

Figure Number	Symbol	Description
1	Rewards Lifestriences	Edwards Lifesciences logo
2	○ -⊕:	AC Label: When it is lit, it indicates the power cord is connected to an external AC power source.
3	%	Push Button: Power ON/OFF Power ON/ STANDBY push button, referred to in the text as ON/OFF.
4	3	Push Button: Start printer.
5		Push Button: Silence alarm
6		Navigation knob

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2.3.2 Monitor Back

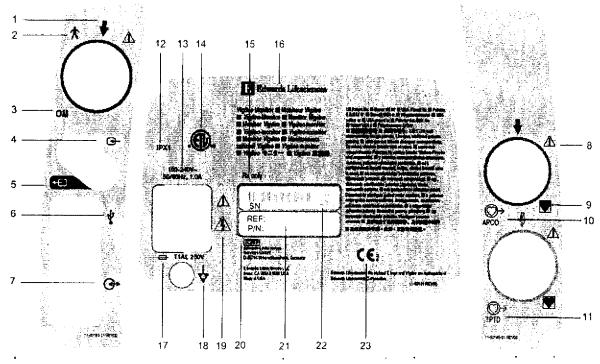


Figure 2-2 Vigileo Monitor Rear Panel Labels

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Table 2-4 Monitor Back Symbols and Connectors

Figure Number	Symbol	Description
1	4	Connector Guide: Use to align connector cable to machine.
2	*	Type B Applied Part: Applied Part is protected against electric shock.
3	OM	Connector Identification: Optical Module connection
4	<u>G</u>	Connector: Analog input
5	←	Connector: Analog output
6	¥	Connector: USB port
7	3	Connector: Serial COM Port
8	<u> </u>	Caution: Read accompanying documents
9		Type CF Applied Part: Applied Part is protected against electric shock, having an F-type isolated (floating) applied part. Intended for direct cardiac application.
10	© → APCO	Connector Identification: APCO connector
11	©→ TPTD	Connector Identification: Thermodilution connector (future option)
12	IPX1	Degree of case waterproofing: Case provides protections against vertically falling water drops
13	160-240V- 50/60Hz, 1.0A	Alternating Current Voltage
14		ETL Certification
15	Reconty	Caution: Federal (USA) law restricts this device to use by, or on the order of, a physician.
16	Edwards Lifestiences	Edwards Lifesciences logo

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В

Table 2-4 Monitor Back Symbols and Connectors

Figure Number	Symbol	Description
17	2.00 m/s	Replacement fuse specification
18	ा . ▽	Equipotential Grounding Post: The Equipotential Grounding Post may be used by facilities as required by their procedures. (Refer to service manual)
19	A	Attention: Risk of electric shock
20		Authorized representative in the European Community
21	REF P/N:	Refurbished unit Part number Model designation
	SN.	Date of Manufacture
22		Serial Number
23	CE	CE mark: Certification to Annex II of EC Directive No. 93/422/EEC concerning medical devices.

2.4 Monitor Display Symbols

The following symbols are displayed on the Vigileo monitor screen.

Table 2-5 Monitor Display Symbols

Symbol	Description	Color
•	CO/CI Trend Indicator	Yellow
Δ	ScvO ₂ Trend Indicator	Purple
A	SvO ₂ Trend Indicator	Light Blue
A	Alarming.	Alternating Red/Gray
<i>#</i>	Alarm Silence: The audible alarm for the parameter has been silenced for two minutes.	Red (Alternating Red / Gray if Alarming)
*	Alarm Off: The audible alarm for the parameter has been turned off.	Red (Alternating Red / Gray if Alarming)
	Signal Quality Indicator (SQI) bar. Normal Intermediate (moderately compromised) Poor Unacceptable	Green Yellow Red Red
	Numeric 1,2,3, or 4 may appear in the lowest box	

2.5 Shipping Container Symbols

The following table identifies symbols on the shipping carton that indicate environmental conditions required for the care in handling of the packaged monitor during shipping and storage.

Table 2-6 Shipping Container Symbols

Description
Keep contents dry.
Fragile. Handle with care.
This end up.
Do not expose contents to environments above 95% RH or below 10% RH.
Do not expose contents to temperatures in excess of 70 deg C or below -25deg C.
Keep away from direct sunlight.

2.6 Standards Compliance

The *Vigileo* monitor complies with the following standards. See Appendix F: Guidance and Manufacturer's Declaration on page F-1 for additional compliance details.

Table 2-7 Standards Compliance

Standard	Compliant Provisions
EN60601-1:1990/A1:1993/A2:1995/A13:1996	
EN60601-1:1990/A1:2003/A2:1995/A13:1996	Class I Equipment
EN60601-1-1:1990/A1:2003/A2:1995/A13:1996	Type B Applied Part
EN60601-1-2:2001	Type CF Applied Part
EN60601-1-4:1996:2003/A2:1995/A13:1996	
EN60601-2-49:2001	
UL 60601-1:2003	Class I Equipment
	Type B Applied Part
	Type CF Applied Part
CAN/CSA-C22.2 No. 606.1-M90 (R2001)	Class I Equipment
	Type B Applied Part
	Type CF Applied Part
EN60529: /A1:2000	IPX1 Water Drip Protection

	NOTE
(35)	The Vigileo monitor is suitable for use in the patient environment as indicated in EN 60601-1-1.
	NOTE
(S)	This equipment may be used in continuous operation.

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Chapter 3 Quick Start Guide to Operation

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	3.5 Monitoring APCO Using AutoKal			
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3.1 Overview

This chapter provides information for immediate use of the *Vigileo* monitor and is intended for experienced clinicians and users of bedside monitors.

3.2 Scope

The Quick Start Guide to Operation is intended only as a checklist for operating the *Vigileo* monitor. Users should thoroughly read this manual before attempting to use this instrument.



WARNING

The *Vigileo* monitor is intended for use only as an adjunct in patient assessment. This instrument must be used in conjunction with patient clinical signs and symptoms. Read this operator's manual carefully before attempting to use the Edwards Lifesciences *Vigileo* monitor.

Before using the *Vigileo* monitor, thoroughly read the directions for catheter use provided with each catheter for complete description, instructions, warnings, cautions, and specifications.

Accessory equipment connected to the monitor must be certified according to IEC/EN 60950 for data-processing equipment or IEC/EN 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC/EN 60601-1-1 systems requirements.



WARNING

Improper use of the *Vigileo* monitor could present a hazard to the patient. Carefully read the "Warnings" section of this manual (in Chapter 2: *Safety and Symbols*) before using the instrument.

3.3 Starting Operation

- 1. Attach the power cord securely to the *Vigileo* monitor. Connect the other end to an AC power outlet. The AC indicator will illuminate.
- 2. Press on the front panel to turn the Vigileo monitor ON. The screen will display an opening message, indicating that a Power-On Self-Test (POST) is being performed.



CAUTION

The only way to remove power from the monitor is to unplug the power cord from its power source.

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3.3.1 Entering Patient Information and BSA

When the POST has completed and no malfunction has been detected, the monitor displays the patient information and body surface area (BSA) entry screen. Patient information must be entered before cardiac output monitoring can occur.

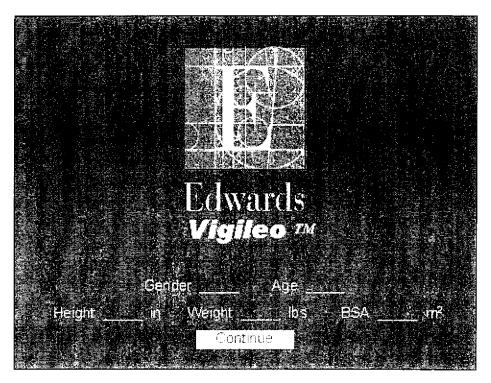


Figure 3-1 Patient Data Entry Screen

- 1. Rotate and press the navigation knob to select the desired entries.
- 2. Press Continue to confirm selection. The Home screen displays.



NOTE

If power is restored within 60 seconds, the Vigileo monitor will attempt to start 1.PCD if I was running when power was lost. The monitor will also attempt to recall SvO_2 calibration data from the Optical Module if it was calibrated when power was lost.

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3.4 Monitoring ScvO₂/SvO₂

\wedge	CAUTION
	Performing an <i>in vitro</i> calibration after the catheter has been inserted into the patient will yield erroneous calibration.
\wedge	CAUTION
	The catheter and the calibration cup must be dry for an accurate <i>in vitro</i> calibration. Flush the catheter lumen only after the <i>in vitro</i> calibration has been completed.

- Connect the Optical Module to the ScvO₂/SvO₂ color-coded connector on the back of the *Vigileo* monitor. Allow 20 minutes for the Optical Module to warm up.
- 2. Connect the catheter to the Optical Module.
- 3. Rotate the navigation knob to highlight the ScvO₂/SvO₂ Frame and press to display the Oximetry Menu.



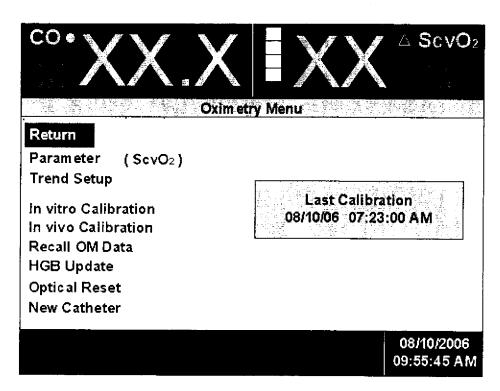


Figure 3-2 Oximetry Frame Menu for ScvO₂ Parameter

- Rotate the navigation knob to highlight Parameter and then select SevO₂ or SvO₂.
- **5.** *Rotate* the navigation knob to select *In vitro* Calibration. You will see the following message:

Enter either HGB or Hct, then select Calibrate.

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B

- **6.** Rotate the navigation knob to select **HGB** (hemoglobin) or **Hct** (Hematocrit), then enter the lab value if available or otherwise use the default values.
- 7. Select Calibrate. You will see the message:

In vitro calibration in progress. Ready in 20 seconds.

When the countdown reaches 0 seconds you will see the following message:

In vitro calibration OK.
Insert catheter
then select Start.

8. Insert the catheter in the patient and select Start.

3.5 Monitoring APCO Using AutoKal

- Connect the Patient APCO Cable to the APCO connector at the back of the *Vigileo* monitor. Align the arrows at the top of the cable connection on the monitor to the arrow on the APCO Cable.
- **2.** Connect the green end of the APCO Cable to the green capped Edwards Lifesciences APCO disposable pressure transducer.
- 3. Assemble and flush the disposable components according to APCO disposable pressure transducer directions for use and connect to the patient's arterial catheter.
- **4.** Rotate the navigation knob until the CO Frame is outlined in yellow and then press the knob.
- **5.** From the CO Frame Menu, *rotate* the navigation knob until Parameter is highlighted.

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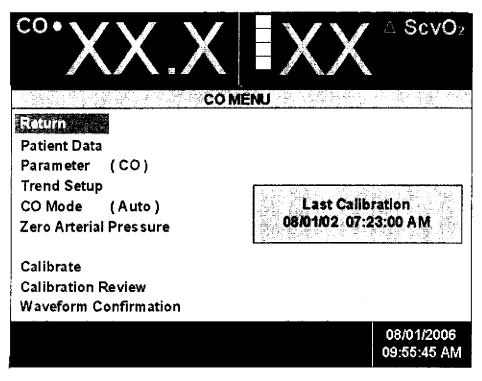
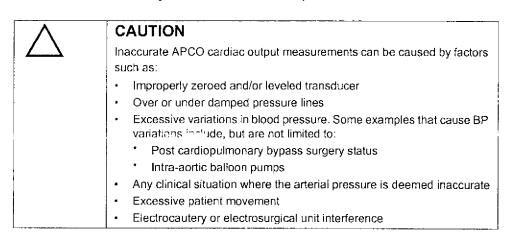


Figure 3-3 CO Frame Menu

- **6.** Select **CO** or **CI** and then *press the* knob to lock in your selection.
- 7. Rotate the navigation knob to highlight Calibration Type and then press the knob.
- 8. Select Auto and then press the knob to lock in your selection.



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3.5.1 Zero Arterial Pressure

Use the Zero Arterial Pressure Screen to zero the transducer to atmospheric air. After the APCO transducer has been assembled and flushed according to the directions for use, and leveled to the patient's phlebostatic axis, the APCO disposable pressure transducer can be zeroed to atmospheric air.

- 1. *Rotate* the navigation knob until the CO Frame is highlighted and then *press the* knob. The CO Frame menu displays.
- 2. Rotate the navigation knob until **Zero Arterial Pressure** is highlighted and then *press the* knob. You will see the message:

Select Zero when the pressure value is stable.

- **3**. *Rotate* the knob to select **Zero**.
- 4. Select **Return** and *press the* knob.

Cardiac output values will be displayed in the CO Frame on the upper left side of the screen.

Use the Waveform Confirmation screen to assess the quality of the arterial waveform and perform a frequency response test if necessary.

3.5.2 Manual CO Calibration

The optional Manual Calibration is provided to calibrate the monitor using patient-specific flow characteristics for continuous CO monitoring. When Manual Calibration option is selected, a 15-minute Calibration Duration timer starts when the Calibrate option is selected.

If the timer expires before the Finish option is selected on the Manual CO Calibration Screen, the calibration is cancelled and the CO Manual Calibration Finish screen is displayed.

See Chapter 6: APCO Monitoring on page 6-1 for details.

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Chapter 4 Unpacking, Installation and Initial Set Up

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4.1 Overview

This chapter covers the unpacking and installation and initial setup of the *Vigileo* monitor. The monitor may require the use of accessories that need to be connected to the monitor, depending on the parameter configuration and user application.

This chapter also describes the Power-On Self-Test (POST) and language selection.

4.2 Unpacking

Examine the shipping container for any signs of damage that may have occurred during transit. If you do detect any damage, we recommend you photograph the package.

Examine the contents of the shipping container. Perform a visual inspection of the monitor, cables and accessories. Report any evidence of external damage to the monitor, frayed cords, or broken or bent connector pins.

The monitor and accessory items may be delivered separately. We recommend you confirm receipt of all ordered equipment.

4.3 Accessories

The following accessories are required to display specific monitored and calculated parameters.

Table 4-1 Parameter Monitoring Accessories

<u> </u>	Monitored and Calculated Parameters			
Accessory	APCO	ScvO ₂ /SvO ₂	SVR	sv
Edwards approved power cord	•	•	•	•
Edwards APCO cable	•		•	•
Optical module		•		
Analog Input Cable(s)			•	

Contact your local Edwards Lifesciences representative for information on printers and printer cables that are compatible for use with the *Vigileo* monitor.

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4.4 Monitor Installation

4.4.1 Environmental Specifications

Table 4-2 Environmental Specifications

Parameter	Value		
Operating temperature without Optical Module	0 to 50°C		
Operating temperature with Optical Module	10 to 37°C		
Storage Temperature	-25 to 70°C		
Relative Humidity, Operating and Storage	10% to 95%, non-condensing		
Operating Atmospheric Pressure	696 to 1013 hPa		



WARNING

Explosion Hazard! Do not use the monitor in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.



WARNING

Make sure all equipment and accessories connected to the monitor are properly grounded.



WARNING

Make sure the *Vigileo* monitor is securely mounted, and that all cords and accessory cables are appropriately arranged to minimize the risk of damage to patients, users or the equipment.



WARNING

To prevent injury, do not use a damaged Vigileo monitor or accessory.



WARNING

Use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the *Vigileo* monitor.



WARNING

Refer to the directions provided with each accessory for specific instructions on accessory placement and use, and for relevant WARNINGS, CAUTIONS, and SPECIFICATIONS.



WARNING

The analog and digital communication ports of the monitor share a common ground that is isolated from the catheter interface electronics. When connecting multiple devices to the *Vigileo* monitor, all devices should be provided with isolated power to avoid compromising the electrical isolation of any of the connected devices.

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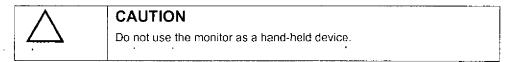
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\triangle	CAUTION Do not expose the Vigileo monitor to extreme temperatures.
\triangle	CAUTION Do not obstruct the Vigileo monitor ventilation openings.
\triangle	CAUTION Use Edwards-compatible accessories only to avoid damage to the monitor and to ensure accuracy of patient information.
\triangle	CAUTION When connecting the <i>Vigileo</i> monitor to any external device, refer to the device's instruction manual for complete instructions. Verify proper operation of the system before clinical use.

4.5 Mounting Recommendations

Securely mount the *Vigileo* monitor according to your institution's practices. Optional mounting accessories can be purchased from approved medical equipment suppliers. Contact your local Edwards representative for recommendations on mounting carts, racks or other options.



4.6 Connecting the Monitor

After the monitor is securely mounted, attach the power cord supplied with the monitor at the back and connect it to a hospital-grade power outlet.





NOTE

The Vigileo monitor automatically adjusts for power voltages from 100 to 240 VAC.



WARNING

Do not use extension cords or multiple socket devices to connect power to the monitor. Do not use any other detachable power cords other than the power cord provided.



CAUTION

The only way to remove power from the monitor is to unplug the power cord from its power source.

See Appendix A: Specifications on page A-1 for information about the physical, electrical, thermal, and atmospheric environments.

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4.7 Connecting the OM Cable

WARNING
Refer to the directions for use provided with each catheter for specific instructions on catheter placement and use, and for relevant WARNINGS, CAUTIONS and NOTES.
WARNING Do not use a damaged catheter or one with exposed electrical contacts.
WARNING Do not use any catheter that has been used previously.

- Connect the Optical Module to the ScvO₂/SvO₂ color-coded connector on the back of the *Vigileo* monitor.
 Allow 20 minutes for the Optical Module to warm up.
- 2. Connect the catheter to the Optical Module.

\wedge	CAUTION
	Prior to catheter insertion, refer to directions for use provided with each catheter for complete description, instructions, warnings, cautions and specifications.

4.8 Connecting the APCO Cable

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WARNING
Refer to the directions for use provided with each Disposable Pressure Transducer for specific instructions on Disposable Pressure Transducer placement and use, and for relevant WARNINGS, CAUTIONS and NOTES.
WARNING
Do not use a damaged Disposable Pressure Transducer or one with exposed electrical contacts.
WARNING
Do not use any Disposable Pressure Transducer that has been used previously.

- Attach the Disposable Pressure Transducer end of the Patient APCO Cable to the green connector on the Edwards Disposable Pressure Transducer.
- **2.** Connect the Patient APCO Cable to the *Vigileo* monitor back panel APCO connector.
- **3.** Verify the Edwards Disposable Pressure Transducer is properly connected to the patient according to the directions for use.

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CAUTION

Prior to connection of the pressure transducer, refer to directions for use provided with each Disposable Pressure Transducer for complete description, instructions, warnings, cautions and specifications.

4.9 Initial Startup

The POST (power on self-test) is performed each time you turn on the monitor. The POST verifies the monitor meets basic operating requirements by exercising the critical hardware components. Each time you start the monitor, you will be able to set your operational defaults such as language and date and time format.



WARNING

The *Vigileo* monitor is intended for use only as an adjunct in patient assessment. This instrument must be used in conjunction with patient clinical signs and symptoms. Read this Operator's Manual carefully before attempting to use the Edwards Lifesciences *Vigileo* monitor.



WARNING

Do not to use a defibrillator while the monitor is connected to the patient.

Each time you turn on the monitor, it performs a self-test. The self-test verifies the monitor meets basic operating requirements by exercising the critical hardware components. Each time you start the monitor, you will be able to set your operational defaults such as language and date and time format.

4.9.1 Starting the Monitor



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- 1. *Press* the front-panel On/Off button to turn on the monitor.
- 2. A tone sounds and the following POST screen displays.

While this screen is displayed, the monitor is booting up and performing the POST. The screen displays for at least five seconds with the bar indicating the POST progress. When the boxes reach the right side of the bar, the diagnostic tests are complete.

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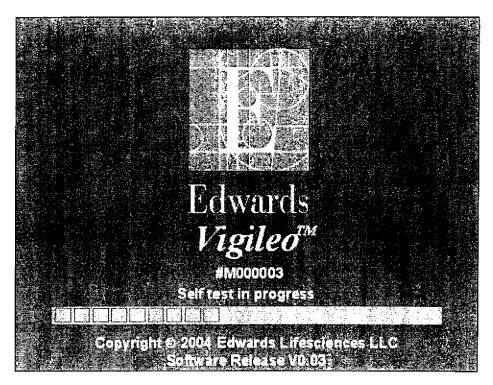


Figure 4-1 Power-On Self Test Screen



NOTE

If the diagnostic tests detect an error condition, an Error Screen will replace the POST Screen. For help, see Chapter 12: Troubleshooting on page 12-1 or Appendix E: System Care, Service and Support on page E-1. Otherwise, contact Edwards Lifesciences for technical support.

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4.10 Language Selection

After the POST successfully completes, you will see the language selection screen. English (US) is selected by default.

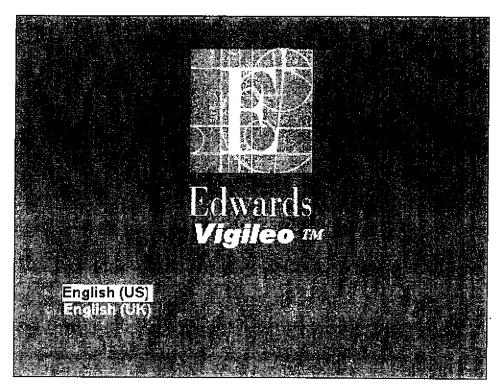


Figure 4-2 Language Selection Screen

- 1. Rotate the navigation knob until the appropriate language is highlighted.
- 2. *Press* the knob to make your language selection. This language becomes the default until changed.

All text will be displayed and printed in the selected language. In addition, the following system settings will apply:

If English (US) is selected:

- International Units No
- All parameters that can be represented in two different units of measure are displayed in their non-international units format.
 Time Format - 12 hour; Date Format - MM/DD/YYYY

If English (UK)

- International Units Yes
- All parameters that can be represented in two different units of measure are displayed in their international units format.
 Time Format - 24 hour; Date Format - DD.MM.YYYY

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After the language selection has been confirmed, you can enter new patient information and start monitoring. See Chapter 6: APCO Monitoring on page 6-1 for detailed instructions on entering patient data.

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Chapter 5 Monitor Display, Controls, Alarms and Indicators

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5.1 Overview

This chapter provides a brief overview of the monitor front and back, using the navigation knob and details about each frame. Details on performing the functions available from each frame are provided in Chapters 6 through 10.

5.2 Monitor Front Panel Display, Controls and Connectors

All functions are performed from the front of the monitor, with cables connecting to the back. All data is viewed on the general monitoring screen which is divided into five frames.

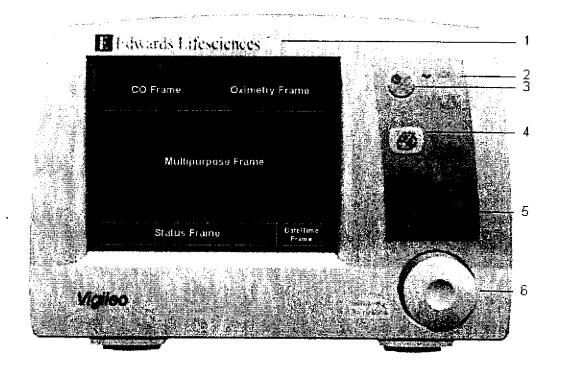


Figure 5-1 Monitor Front Panel Descriptions

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Table 5-1 Monitor Front Panel Symbols and Connectors

Figure Number	Symbol	Description
1	Edwards Lifestiences	Edwards Lifesciences logo
2		AC Label: When it is lit, it indicates the power cord is connected to an external AC power source.
3	%	Push Button: Power ON/OFF Power ON/ STANDBY push button, referred to in the text as ON/OFF.
4		Push Button: Start printer.
5	*	Alarm Silence: Silences technical alarms indefinitely and physiological alarms for two minutes. After alarm cause is cleared, renewed alarm sound requires additional button operation to silence it. The CO and Oximetry Frames with an alarming parameter will display a bell with a single slash for that alarm silence period.
6		Navigation knob

5.2.1 Using the Navigation Knob

The navigation knob allows you to select frames, menu options, settings, and to execute menu functions by *rotating* and/or *pressing* the knob.

- 1. *Rotate* the knob clockwise to move the solid yellow frame highlight clockwise from frame to frame.
- **2.** *Rotate* the knob counterclockwise to move the solid yellow frame highlight counterclockwise from frame to frame.
- **3.** *Press* the knob when a frame is nightighted to activate the frame's menu or function.

5.2.2 Using the Keypad

The *Vigileo* monitor keypad consists of fixed-function buttons on a membrane keypad. The buttons are described in the following table.

Table 5-2 Monitor Keypad Descriptions

Symbol		Description	
%	On/Off	Power ON/OFF Power ON/STANDBY push button, referred to in the text as ON/OFF.	
○ -©:	AC Label	When it is lit, the AC label indicates the power cord is connected to an external AC power source.	
4	Print	Displays a printer icon used to initiate the printing of screen.	
A /	Alarm	Toggles between audible tones and silence.	
<i>*</i>	Silence	WARNING Do not turn off the alarms in situations in which patient safety could be compromised.	

If two or more buttons are pressed at the same time, the system responds only to the first one detected. A confirmation tone sounds in response to each valid key press. A different tone indicates an invalid key press.

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5.3 Monitor Back Connectors

This chapter describes the connectors on the back of the *Vigileo* monitor. See Chapter 2: Safety and Symbols on page 2-1 for a description of the various icons and labels included on the back.

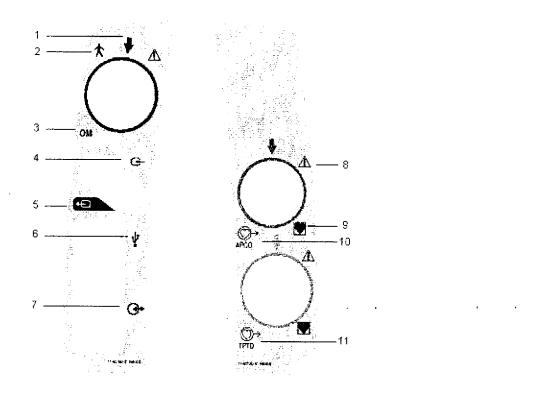


Figure 5-2 Monitor Back Connectors

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Table 5-3 Monitor Back Connector Descriptions

Figure Number	Symbol	Description
1	#	Connector Guide: Use to align connector cable to machine.
2	*	Type B Applied Part: Applied Part is protected against electric shock.
3	OM	Connector Identification: Optical Module connection
4	<u>G</u>	Connector: Analog input
5	\leftarrow	Connector: Analog output
6	¥	USB Connector and label for printer.
7	⊕ >	Connector: Serial COM Port
8 .	1	Caution: Read accompanying documents
9		Type CF Applied Part: Applied Part is protected against electric shock, having an F-type isolated (floating) applied part. Intended for direct cardiac application.
10	Ø→ APCO	Connector Identification: Arterial Pressure Cardiac Output connection
11	©→ TPTD	Connector Identification: Thermodilution connector (future option)

5.4 Monitor Frames

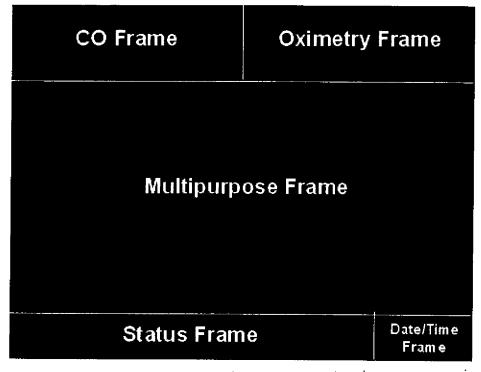


Figure 5-3 Main Monitor Screen

5.4.1 Fixed Frames

The following fixed frames are always visible:

- CO Frame
- Oximetry Frame
- Status Frame
- Date/Time Frame

The Multipurpose Frame displays menus and monitoring results.

Rotate the navigation knob to select a frame. A frame can be selected when it is highlighted with a yellow outline. If two minutes pass with no activity (knob rotation, knob press or key press) the highlighting disappears. In the following example, the Oximetry Frame is highlighted and can be selected by pressing the knob.

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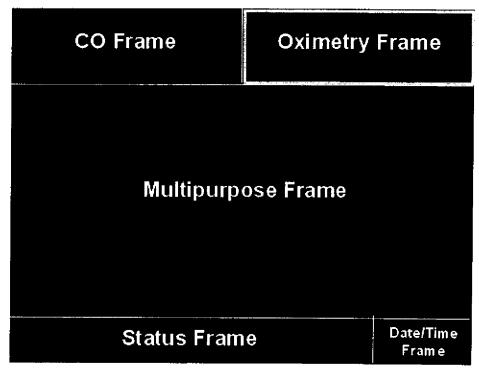


Figure 5-4 Main Monitor Screen with Oximetry Frame Selected

Multipurpose Frame - Data Display 5.4.2

The Multipurpose Frame displays various setup screens as well as display of all data currently being monitored.

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5.5 CO Frame

The CO Frame displays the most recently measured value for Cardiac Output or Cardiac Index. The frame displays a label, the CO/CI trend symbol ●, the value, and an alarm icon.



Figure 5-5 CO Frame

If any fault occurs during CO measurement, the numeric display for CO or CI is frozen at the last measured or calculated value and a time stamp is displayed representing the point in time that the value was measured.



Figure 5-6 CO Frame with Time-Stamp

When you highlight the CO Frame and then *press the* knob, the CO Menu displays, allowing you to select CO monitoring functions, calibration types, menus and screens.

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5.6 Oximetry Frame

The Oximetry Frame displays the most recently measured value for central or mixed venous oxygen saturation. The frame displays a label, a trend symbol (\triangle for SevO₂ or \blacktriangle for SvO₂), the value, an alarm icon, and a signal quality indicator (SQI) bar.



Figure 5-7 Oximetry Frame

If any fault occurs during oximetry measurements, the numeric display for ScvO₂/SvO₂ is frozen at the last measured value and a time stamp is displayed representing the point in time that the value was measured.



Figure 5-8 Oximetry Frame

5.7 Status Frame

The Status Frame displays the highest priority CO and Oximetry status messages. If there is only one status message, it is displayed continuously. If there are both CO and Oximetry status messages, each message displays for two seconds, then switches to the other message.



Figure 5-9 CO Status Message

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5.8 Date/Time Frame

The Date/Time Frame displays the current system date and time. The time and date display formats are set in the Date/Time Frame Menu which displays when you select the Date/Time Frame and *press the* navigation knob.



Figure 5-10 Date/Time Frame

5.8.1 Setting Date and Time Defaults

The Time and Date Menu is used to set the current time and date, and to select the time and date display format

- 1. Rotate the navigation knob until the Date/Time Frame is highlighted.
- 2. Press the knob to display the Time and Date Menu.

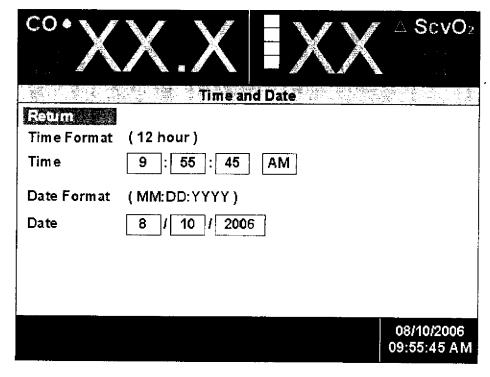


Figure 5-11 Time and Date Menu

- 3. Rotate the navigation knob to highlight Time Format.
- **4.** Press the knob. The highlighting shifts to the value field.
- **5.** Rotate the navigation knob to change the selection.
- **6.** *Press* the knob to confirm your selection. The selected format will display next to **Time Format** and the Date/Time Frame will be updated to the selected format.

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- 7. Rotate the navigation knob to highlight Date Format.
- **8.** *Press* the knob. The highlighting shifts to the value field.

To set the date format to 12/4/2003, select MM:DD:YYYY. To set the date format to 4.12.2003, select DD:MM:YYYY.

- 9. Rotate the navigation knob to select your preference.
- **10.** *Press* the knob to confirm your selection. The selected format will display next to Date Format.

5.8.2 Setting the Current Date

- 1. Rotate the navigation knob to highlight **Date**.
- 2. Press the knob. The first date field is highlighted.
- **3.** *Rotate* the navigation knob to highlight the date field you want to set and then *press the* knob.
- **4.** *Rotate* the navigation knob clockwise to advance the date or counter-clockwise to decrease the date value and then *press* the knob to confirm your selection.
- **5.** Repeat steps 3 through 5 for the remaining fields.
- **6.** To confirm the date setting and exit the menu, select **Return** and then *press* the knob. The Time/Date Frame will be updated to the new date.

5.8.3 Setting the Current Time

- 1. *Rotate* the navigation knob to highlight **Time** and then *press* the knob. The first time field is highlighted.
- **2.** Rotate the navigation knob to highlight the time field you want to set and then *press* the knob.
- **3.** *Rotate* the navigation knob clockwise to advance the time or counter-clockwise to decrease the time value and then *press* the knob to confirm your selection.
- **4.** Repeat steps 2 and 3 for the remaining fields, including AM and PM if you are using a 12-hour clock.
- 5. To confirm the time setting and exit the menu, select **Return** and then *press* the knob. The Time/Date Frame will be updated to the new time.

5.9 Multipurpose Frame

The Multipurpose Frame displays the fixed frame menus and all data being monitored.

5.9.1 All Data

The All Data Screen displays and continuously updates the values of six selectable parameters.

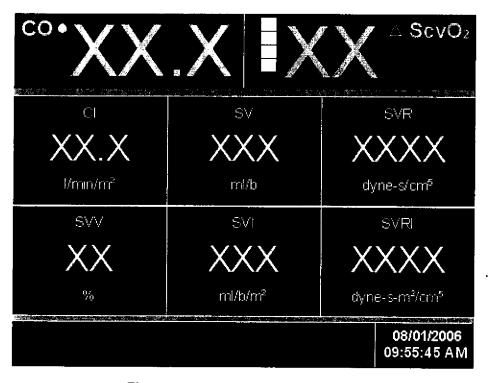


Figure 5-12 All Data Monitoring Screen

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5.10 Alarms

The *Vigileo* monitor sounds tones in response to monitor parameters that fall outside of defined limits and in response to faults or error conditions. In addition, a continuous tone shutdown alarm sounds if the monitor cannot continue to monitor, for example, the software is shutting down due to a hardware error condition.

5.10.1 Limit Alarms

When an Alarm activates, an audible Alarm tone is initiated. When the reason for the audible Alarm tone is cleared, and there is no other reason for the audible Alarm tone to sound, the audible Alarm tone stops.

Alarms are "non-latching," that is the alarm ceases once the parameter returns within limits. Once active, the alarm state is indicated by:

- Blinking alarming value and alarm symbol
- · Audible alarm indicators

High/Low alarms for ScvO₂, SvO₂, CO and CI can be turned off from each parameter's sub-menu.

If an alarm has been temporarily silenced, a red bell icon with a single slash through it appears in the CO and Oximetry Frames. A red bell icon with a cross through it appears if alarms have been turned off for these parameters.



5.10.2 Fault/Alert Alarms

A fault requires operator intervention before monitoring can resume. If a fault causes processing to stop, the fault message is displayed and accompanied by two rapid beep tones that continue until silenced by the operator (using the Alarm Silence keypad button) or until the condition clears. In many cases, fault conditions that prevent CO monitoring will not prevent oximetry monitoring.

An Alert is intended to provide help in qualifying the measurement results. These messages may appear on the screen without auditory notification.

Audible Alarm tones are higher priority than audible Fault/Alert tones. If there is a reason for both tones to sound, the Audible Alarm tone sounds.

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5.10.3 Alarm Silence Keypad Button



When the Alarm Silence keypad button is pressed, all currently active audible Limit Alarm tones are temporarily silenced for two minutes. The Alarm Silence icon (alarm symbol with a single slash through it) is displayed in the CO Frame and/or Oximetry Frame if the parameter is in an alarm condition. When the silence period expires, the Alarm Silence

icon is removed from the display and if any Limit Alarm condition is present, the audible Limit Alarm tone starts.

If more than one Limit Alarm condition is present at the time the Alarm Silence keypad button is pressed, a single press temporarily silences all of the active audible Limit Alarm tones.



NOTE

If a shutdown alarm occurs during an alarm silence period, the Shutdown Alarm tone will still sound.

If no alarm is active when the Alarm Silence Keypad button is pressed, it has no effect.

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5.10.4 Configuring Alarm Limits

Select the **Trend Setup** option to set the scale and alarm settings, and enable or disable audible alarms. Selecting the **Return** option will return you to the Frame Menu with the current settings. If two minutes elapse with no knob activity, any selections in progress are lost and the screen returns to the previously active Multipurpose Frame Screen.



WARNING

Do not turn off the alarms in situations in which patient safety could be compromised.

- 1. *Rotate* the navigation knob to highlight the CO Frame or the Oximetry Frame and then *press* the knob to select. The Frame menu displays.
- 2. Select the **Trend Setup** option and *press* the knob.

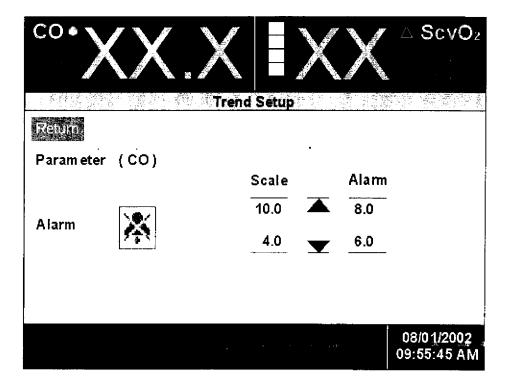


Figure 5-13 CO or Oximetry Trend Setup Menu

- 3. Rotate the navigation knob to highlight Alarm and then press the knob.
- **4.** Rotate the navigation knob to cycle through the available options and then press the knob to lock in your selection.
- **5.** Select **Return** to return to the Frame Menu.

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Chapter 6 APCO Monitoring

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6.1 Overview

In CO monitoring mode, the *Vigileo* monitor continuously displays cardiac output measurements. CO, a time-average value, is numerically displayed in the CO Frame at the upper left corner of the screen.

In addition, estimates of CO values are calculated at approximately 20-second intervals.

CO is displayed in liters/minute (l/min), and CI is displayed in liters/minute/body surface area (l/min/m²).

6.2 CO Frame

The CO Frame displays the most recently measured value for Cardiac Output or Cardiac Index. The frame includes the following:

- Label field
- Trend symbol ("•")
- Value field
- Alarm icon



Figure 6-1 CO Frame



Figure 6-2 CO Frame with Time-Stamp

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6.2.1 Selecting the CO Frame

1. Rotate the navigation knob until the CO Frame is highlighted.

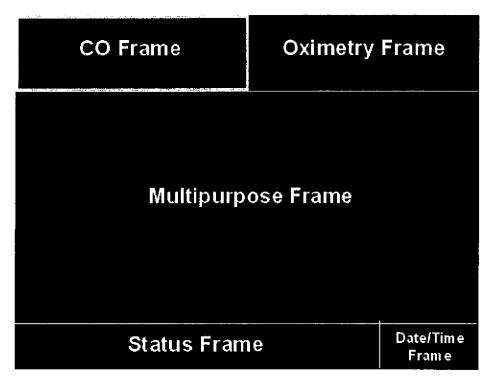
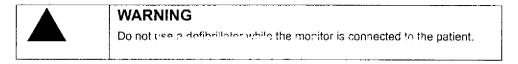


Figure 6-3 Selecting the CO Frame

2. Press the knob. The CO Frame Menu displays.

6.3 CO Frame Menu

The CO Frame Menu allows you to select CO monitoring functions, calibration types, menus and screens.



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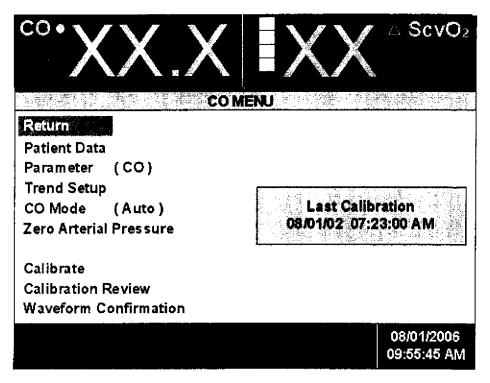


Figure 6-4 CO Frame Menu

6.3.1 CO Frame Menu Navigation

- 1. Rotate the navigation knob to highlight an option and then press the knob.
- 2. Rotate the navigation knob to move between entry fields.

6.3.2 Patient Data

Patient data MUST be entered before CO monitoring can begin. If two minutes elapse with no knob activity, any selections in progress are lost and the screen returns to the previously active Multipurpose Frame Screen.

When you exit the menu, if the CO Mode is "Auto," the Gender, Age, and ESA are defined and the Arterial Pressure has been zeroed, calculation and display of CO values in the CO Frame will begin.

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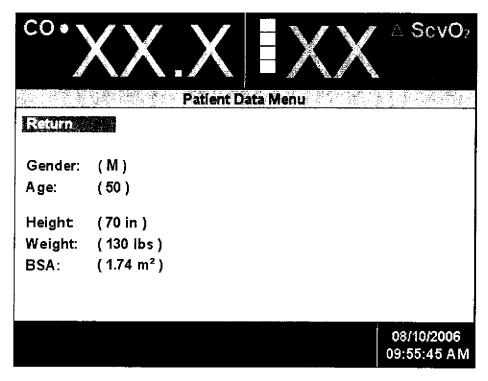


Figure 6-5 Patient Data Menu

- 1. Select the Patient Data option to display current patient information in the Patient Data Menu. You can change any of the patient data from this menu.
- 2. Rotate the navigation knob to highlight an option and then press the knob.
- 3. Rotate the navigation knob to cycle through the available options and then press the knob to lock in your selection.
- 4. Select Return to return to the CO Frame Menu, saving the current settings.

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Table 6-1 Patient Data Parameters

Parameter	Options	Defaults	
Return	Return to the CO Frame Menu, saving any settings	None	
Gender	M (Male) F (Female)	М	
Age	2 to 120 by 1	50	
Weight	2 to 880 lbs by 1 1.0 to 400.0 Kg by 0.5	150 lbs 68.0 kg	
Height	12 to 98 in by 1 30 to 250 cm by 1	60 in 152 cm	
BSA	0.08 to 5.02 m ² by 0.01	1.65 m ²	

6.3.3 Parameter

Use the **Parameter** option to select CO or CI monitoring.

- 1. *Rotate* the navigation knob to highlight the **Parameter** option and then *press* the knob.
- 2. Rotate the navigation knob to select CO or CI.
- 3. Press the knob to lock in your selection.

6.3.4 CO Trend Setup Menu

Select the **Trend Setup** option to set the CO/CI scale and alarm settings, and enable or disable CO/CI audible alarms in the CO Trend Setup Menu. Selecting the **Return** option will return you to the CO Frame Menu with the current settings. If two minutes elapse with no knob activity, any selections in progress are lost and the screen returns to the previously active Multipurpose Frame Screen.



WARNING

Do not turn off the alarms in situations in which patient safety could be compromised.

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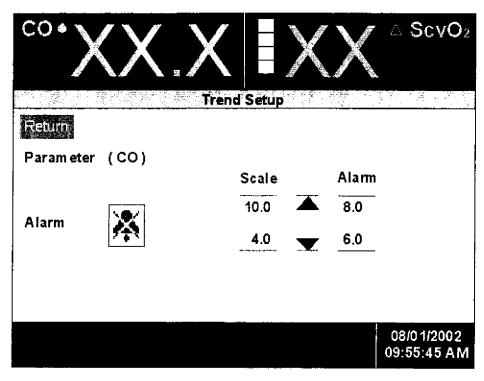


Figure 6-6 Trend Setup Screen

- 1. Rotate the navigation knob to highlight an option and then press the knob.
- **2.** *Rotate* the navigation knob to cycle through the available options and then *press* the knob to lock in your selection.
- 3. Select Return to return to the CO Frame Menu.

Table 6-2 Trend Setup Options

Option	Description	Selection Parameters
Return	Return to the CO Frame Menu, saving any settings	None
Alarm (icon)	Toggle between Alarm Enabled and Alarm Disabled.	Enabled Alarm ICON
		Disabled Alarm ICON
Scale Upper Limit	Set the upper and lower limits. You cannot set an upper limit that is lower than the Lower Limit. Conversely, you cannot set a lower limit that is higher than the Upper Limit.	CO/CI 4.0 to 20.0 by 1.0
Scale Lower Limit		CO/CI 0.0 to 10.0 by 1.0
Alarm Upper Limit		CO - 2.0 to 20.0 by 0.1
		CI - 1.0 to 20.0 by 0.1
Alarm Lower Limit		CO - 1.0 to 19.0 by 0.1
		CI - 0.0 to 19.0 by 0.1

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CO Mode 6.3.5

Use the CO Mode option to select the calibration mode for CO calculations.

- 1. Rotate the navigation knob to highlight the CO Mode option and then press the knob.
- 2. Rotate the navigation knob to select Auto for calculations using AutoKal (automatic calibration) or Manual for manually entering an independent CO value for calibration.
- 3. *Press* the knob to lock in your selection.



NOTE

Manual calibrations do not take effect until the Calibrate option is selected in the CO Frame Menu and the calibration process is completed.

6.4 The Edwards APCO Cable

The APCO cable is a specially-designed cable that connects an APCO disposable pressure transducer and the Vigileo monitor.

6.4.1 Using the APCO Cable

- 1. Check the label on the APCO cable to ensure the cable part number is appropriate for the Vigileo monitor. See Appendix A: Specifications on page A-1.
- 2. Connect the cable to the Vigileo monitor. Match the green connectors at both ends.
- 3. Use a straight in or out motion to connect or disconnect the cable to the APCO pressure transducer. (Refer to the APCO disposable pressure transducers instructions for use).
- 4. Use routine transducer calibration procedures to determine the proper pressure signals are being transmitted.
- 5. Follow the instructions for "Zero Arterial Pressure" on page 6-10 for zeroing the APCO disposable pressure transducer with the *Vigileo* monitor.
- 6. When the cable is not in use, protect the exposed cable connector from fluid spills. Use the cable clip near the transducer connector to store the exposed end. Moisture within the connector may result in cable malfunction or inaccurate pressure readings.

\wedge	CAUTION	
	Always grasp the connector, not the cable, when connecting or disconnecting the cable.	
	CAUTION	
	Do not twist or bend the connectors.	

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6.4.2 Zero Arterial Pressure

Use the Zero Arterial Pressure Screen to zero the transducer to atmospheric air. After the APCO transducer has been assembled and flushed per the directions for use and leveled to the patient's phlebostatic axis the APCO disposable pressure transducer can be zeroed to atmospheric air.

Select the **Zero Arterial Pressure** option to set the zero point for Arterial Pressure in the Zero Arterial Pressure Screen. Selecting the **Return** option will return you to the CO Frame Menu with the current setting.

The Current Arterial Pressure measurement is continuously updated. Measurement units are determined by International/Non-International Units Setup.

When you exit the screen, if the CO Mode is "Auto" and the Gender, Age, and BSA are defined, CO values will be calculated and displayed in the CO Frame will begin.

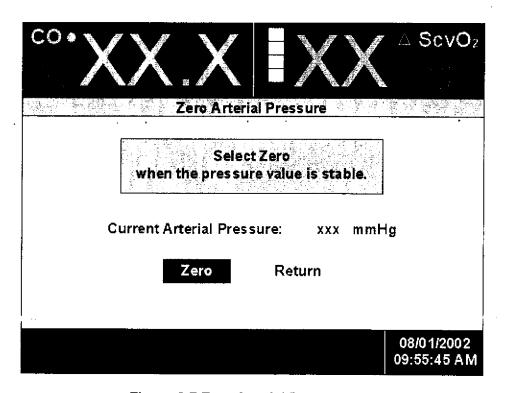


Figure 6-7 Zero Arterial Pressure Screen

- 1. Verify the disposable pressure transducer is leveled to the patient's phlebostatic axis position according to the disposable pressure transducer instructions for use.
- **2.** When the arterial pressure value is stable, *rotate* the navigation knob to select **Zero** and *press* the knob.
- **3.** If the arterial pressure value is stable around zero, *rotate* the navigation knob to select **Return** and *press* the knob.

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NOTE

If the arterial pressure requires too great an offset in order to be zeroed, a warning will be displayed in the Status Frame.

6.5 Calibrate

The Calibrate option is available when Manual is the selected CO Mode. Use the CO Manual Calibration Data Entry screen to enter a cardiac output measured from another cardiac output technology that reflects the patient's current status. When you select the Finish option, you are returned to the CO Frame Menu and the value is then used to calibrate the continuous CO algorithm.

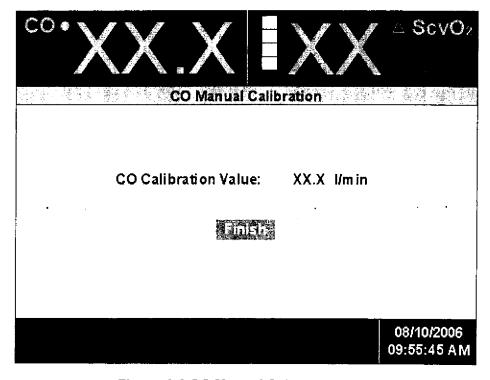


Figure 6-8 CO Manual Calibration Screen

- 1. *Rotate* the navigation knob to highlight the **CO Calibration Value** option and then *press* the knob.
- 2. Rotate the navigation knob to increment or decrement the value. You can select a value from 1.0 to 20.0 for CO Calibration Value.
- 3. Press the knob to lock in the value.
- **4.** Rotate the navigation knob to highlight the **Finish** option and press the knob to display the Manual CO Calibration Finish Screen.

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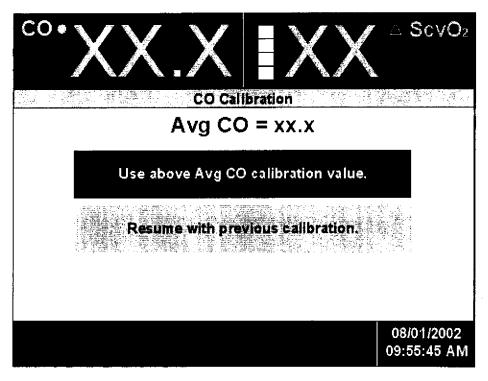


Figure 6-9 CO Manual Calibration Finish Screen

5. Rotate the navigation knob to highlight the Resume with previous calibration option to cancel the manual calibration process and return to the CO Frame Menu.

OR

- 6. Rotate the navigation knob to highlight the Use above Avg CO calibration value option to accept the calibration value. Once accepted, the two options are greyed and the Please Wait message is flashed below the options.
- 7. When the calibration is completed by the system, the CO Frame Menu is displayed.

A 15-minute Manual Calibration Duration timer starts whenever Calibrate is selected. If the timer expires before the Finish option is selected on the Manual CO Calibration Screen, the calibration is cancelled and the Manual Calibration Finish screen is displayed.

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6.6 Calibration Review

The CO Calibration Review Screen displays the last eight CO calibrations. The screen displays until you select **Return** or until two minutes elapse with no knob activity.

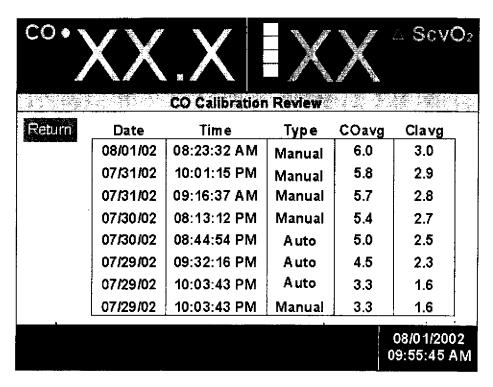


Figure 6-10 CO Calibration Review Screen

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6.7 Waveform Confirmation

Select the **Waveform Confirmation** option to display the arterial pressure waveforms in the Waveform Screen. The Waveform Confirmation screen allows the clinician to assess the quality of the arterial waveform and perform a frequency response test if necessary. The screen displays until you select **Return**.

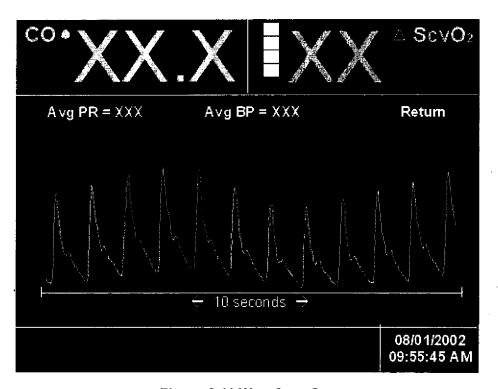
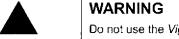


Figure 6-11 Waveform Screen

The graph displays a horizontal 10-second baseline. The vertical axis is autoscaled to the Avg BP value \pm 50 mmHg.

The arterial pressure waveform data sweeps from left to right over a 10 second partied. The Avg PR and Avg BP values are displayed above the waveform. If a value is out of range, the parameter value fields display "----".



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Do not use the Vigileo monitor as a pulse rate or blood pressure monitor.

6.8 CO Calibration Warning Screen

The CO Calibration Warning Screen displays a warning message when a Manual Calibration is being started and the monitor detects a hemodynamically unstable condition.

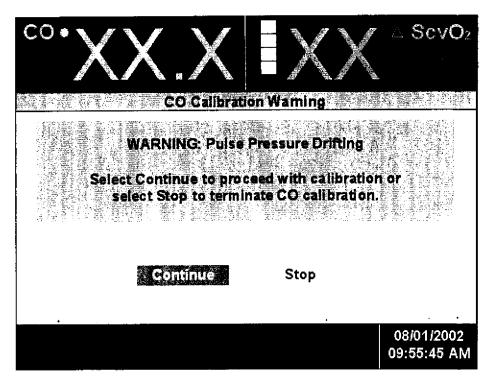


Figure 6-12 CO Calibration Warning Screen

- 1. To continue calibration, wait until the pulse pressure stabilizes.
- 2. Select Continue and *press* the knob.
- 3. To terminate calibration, rotate the navigation knob to Stop and press the knob.

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Chapter 7 Oximetry

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7.1 Overview

This chapter describes procedures for calibration and operation of oximetry (oxygen saturation) measurement on the *Vigileo* monitor. The *Vigileo* monitor is compatible with any of the Edwards Lifesciences oximetry catheters.

7.2 Oximetry Frame

The Oximetry Frame displays the most recently measured value for central or mixed venous oxygen saturation. The frame includes the following:

- · Label field
- Trend symbol ("△"for ScvO₂ and "▲" for SvO₂)
- · Value field
- Alarm icon
- · Signal quality indicator (SQI) bar



Figure 7-1 Oximetry Frame - ScvO₂



Figure 7-2 Oximetry Frame - SvO₂

7.3 Setting Up Oximetry Calibration

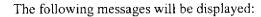
Before you start Oximetry monitoring, you must calibrate the Optical Module. The calibration may be performed *in vitro* (before the catheter is inserted into the patient), or *in vivo* (after the catheter is inserted into the patient). The calibration procedures are the same for all oximetry catheters.

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7.3.1 Catheter Preparation

To connect the Edwards oximetry catheter to the Optical Module for oximetry monitoring:

- Remove a section of the tray lid to expose the Optical Module connector.
- 2. Insert the optical connector, "TOP" side up, into the Optical Module.
- **3.** Insert the connector of the Optical Module into the OM connector at the left rear of the *Vigileo* monitor.





Followed by:

OM Connected, Please Wait

Followed by:

Optical Module Not Calibrated - Select Oximetry Frame to calibrate

7.3.2 Select the Oximetry Menu

1. Rotate the navigation knob to highlight the Oximetry Frame and then press the knob. The Oximetry Frame Menu displays.

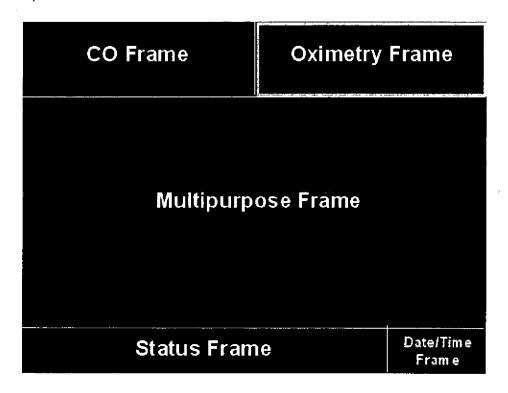


Figure 7-3 Main Monitoring Layout with Oximetry Frame Highlighted

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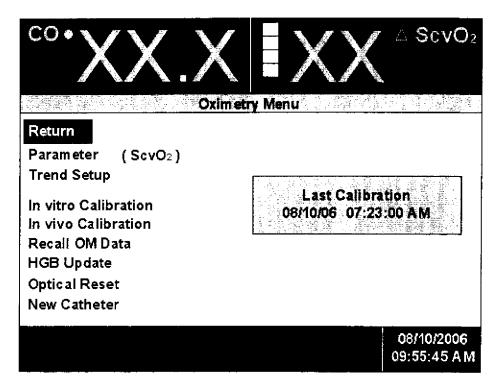


Figure 7-4 Oximetry Frame Menu

7.4 Oximetry Menu

The Oximetry Frame Menu allows you to select between mixed venous oxygen saturation (SvO₂) or central venous oxygen saturation (ScvO₂) monitoring, calibration types, menus and screens.

The menu displays until you select one of the following or until two minutes passes with no knob activity. If the menu closes due to inactivity, any selections are discarded.

7.4.1 Oximetry Menu Navigation

- 1. Rotate the navigation knob to highlight an option and then press the knob.
- 2. Rotate the navigation knob to move between entry fields.

7.5 Parameter

When oximetry is not calibrated, you must select the **Parameter** option and select $SevO_2$ or SvO_2 . Other options are not available until this selection has been made.

- 1. Rotate the navigation knob to highlight the **Parameter** option and then press the knob.
- **2.** Rotate the navigation knob to select $ScvO_2$ or SvO_2 and then press the knob.

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7.6 Trend Setup

Select the **Trend Setup** option to set the ScvO₂/SvO₂ scale and alarm settings, and enable or disable ScvO₂/SvO₂ audible alarms in the Oximetry Trend Setup Menu. Selecting the **Return** option will return you to the Oximetry Frame Menu with the current settings. If two minutes passes with no knob activity, all selections in progress are lost and the screen returns to the previously active Multipurpose Frame Screen.



WARNING

Do not turn off the alarms in situations in which patient safety could be compromised.

- 1. *Rotate* the navigation knob until the Oximetry Frame is highlighted and then *press* the knob. The Oximetry Frame Menu displays.
- 2. Rotate the navigation knob until **Trend Setup** is highlighted and then *press* the knob.

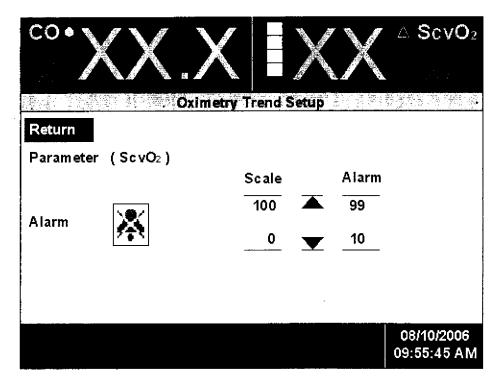


Figure 7-5 Oximetry Trend Setup Screen

- 3. Rotate the navigation knob to highlight an option and then press the knob.
- **4.** Rotate the navigation knob to cycle through the available options and then press the knob to lock in your selection.
- **5.** Select **Return** when you are done and then *press* the knob to close the Trend Setup Menu.

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Table 7-1 Trend Setup Options

Option	Description	Selection Parameters
Return	Return to the Oximetry Menu, sav- ing any settings	None
Alarm (icon)	Toggle between Alarm Enabled and	Enabled Alarm ICON
, , , , , ,	Alarm Disabled.	Disabled Alarm ICON
Scale Upper Limit	Set the upper and lower limits. You	20 to 100 by 10
Scale Lower Limit	cannot set an upper limit that is	0 to 60 by 10
Alarm Upper Limit	lower than the Lower Limit. Conversely, you cannot set a lower limit	20 to 99 by 1
Alarm Lower Limit	that is higher than the Upper Limit.	0 to 60 by 1

7.7 In vitro Calibration

In vitro calibration is performed before the catheter is inserted into the patient, using the calibration cup provided in the catheter packaging.

\wedge	CAUTION
	The catheter and the calibration cup must be dry for an accurate in vitro calibration. Flush the catheter lumen only after the in vitro calibration has been completed.
Λ	CAUTION
	Performing an in vitro calibration after the catheter has been inserted into
	the patient will yield erroneous calibration.

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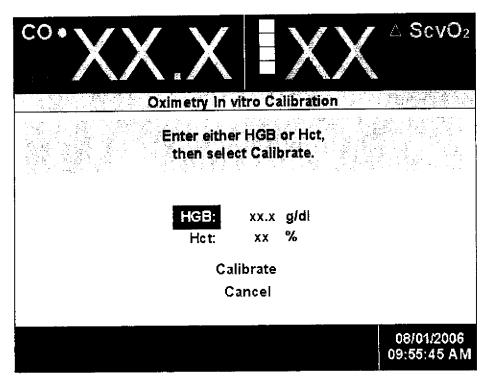


Figure 7-6 Oximetry In vitro Calibration Data Entry Screen

- 1. . Rotate the navigation knob to highlight In vitro Calibration.
- 2. Press the knob. The Oximetry In vitro Calibration screen appears in the Multipurpose Frame in which you can enter the patient's hemoglobin (HGB) or hematocrit (Hct) values, or use the default values provided. To enter new values, follow step 3 through 10.
- 3. To change the HGB value, *rotate* the navigation knob to highlight HGB.
- **4.** *Press* the knob. The displayed value is now highlighted, and may be changed by *rotating* the navigation knob clockwise to increase the HGB value or counterclockwise to decrease the value.
- **5.** When the correct value appears, *press* the navigation knob.
- **6.** To change the hematocrit value, *rotate* the knob to highlight the **Hct** parameter.
- 7. *Press* the knob. The displayed value is now highlighted as well, and may be changed by *rotating* the navigation knob clockwise to increase the Hct value or counterclockwise to decrease the value.
- **8.** When the correct value appears, *press* the navigation knob.
- 9. After entering the lab values, or if you wish to use the default values shown in the menu (11.5 g/dl (7.1 mmol/l) for HGB and 35% for Hct), *rotate* the navigation knob to highlight **Calibrate**.
- **10.** *Press* the knob. The menu screen displays the message shown below. The remaining time counts down each second.

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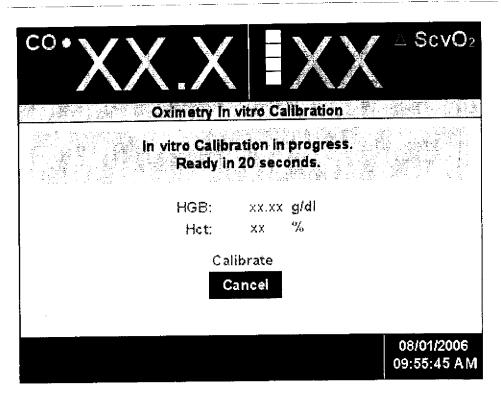


Figure 7-7 Oximetry In vitro Calibration in Progress

Table 7-2 In vitro Calibration Options

Option	Description	Selection Parameters
HGB (g/dl)	Enter an HGB value to use for calibration.	4.0 to 20.0 by 0.1
HGB (mmol/l)		2.5 to 12.4 by 0.1
Hct (%)	Enter an Hct value to use for calibration.	12 to 60 by 1
Calibrate	Starts ScvO ₂ /SvO ₂ calibration to begin. The screen changes to <i>In vitro</i> Calibration In Progress	None
Cancel	Discards all selections.	None

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7.7.1 Completing the Oximetry In vitro Calibration

When the Oximetry *In vitro* Calibration successfully completes, the following screen displays.

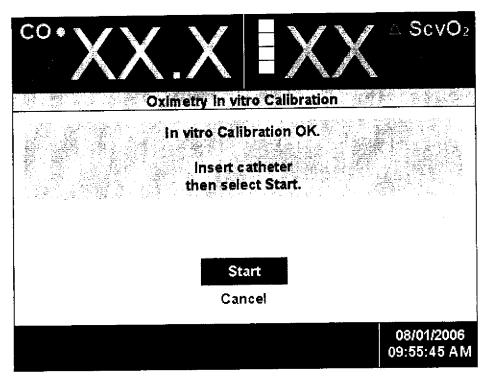


Figure 7-8 Oximetry In vitro Calibration OK

1. Insert the catheter in the patient and select **Start**. The displayed message changes to:

Optical Module Update in progress. Do not disconnect Optical Module. Ready in xx seconds

Where xx is updated every second for a total interval of 25 seconds.



CAUTION

Do not disconnect the optical module while calibration and patient data are being transferred from the Vigileo monitor.



NOTE

Insert catheter into the patient as described in the catheter Directions for Use before selecting **Start**.

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7.7.2 In vitro Calibration Error

If the *Vigileo* monitor is unable to perform an *In vitro* Calibration, the following screen displays:.

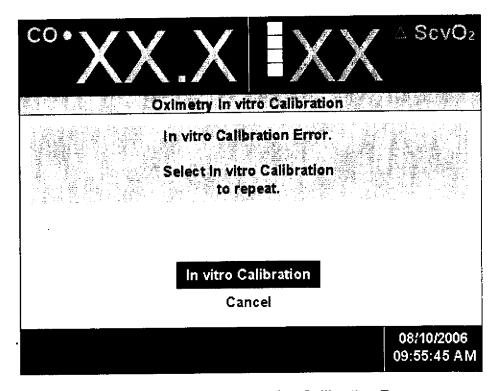


Figure 7-9 Oximetry In vitro Calibration Error

1. Select *In vitro* Calibration to repeat the oximetry calibration process, or Cancel to return to the beginning of the oximetry calibration process.

7.7.3 Cancelling the Calibration Process

Calibration can be cancelled at any time during the oximetry calibration process. When calibration is cancelled, any oximetry parameter values are discarded and the screen returns to the Oximetry Frame Menti.

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1. Rotate the navigation knob to select Cancel.

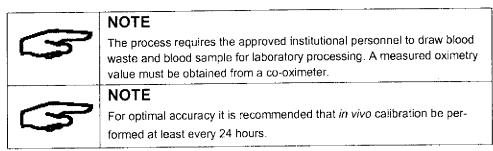
5

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7.8 In vivo Calibration

In vivo calibration is performed after the catheter has been inserted into the patient.

WARNING
Refer to the directions provided with each accessory for specific instructions on accessory placement and use, and for relevant WARNINGS, CAUTIONS, and SPECIFICATIONS.
WARNING
Do not use a damaged catheter or one with exposed electrical contacts.



1. Rotate the navigation knob to highlight *In vivo* Calibration. The monitor begins the calibration process as shown in the following figure.

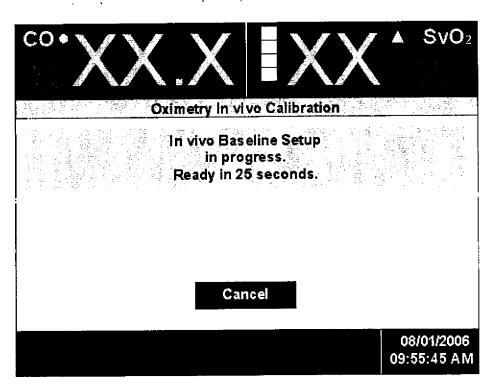


Figure 7-10 Oximetry In Vivo Calibration

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If Baseline Setup is unsuccessful, one of the following messages will be displayed in the Oximetry *In vivo* Calibration Screen:

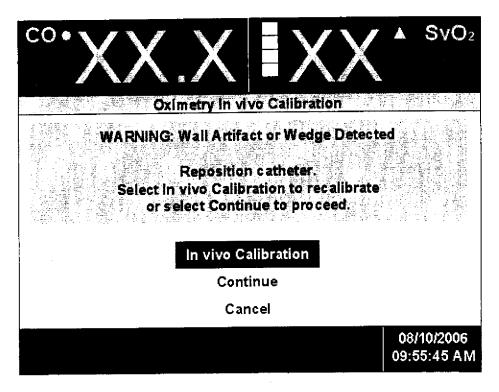


Figure 7-11 Oximetry In vivo Calibration Catheter Error

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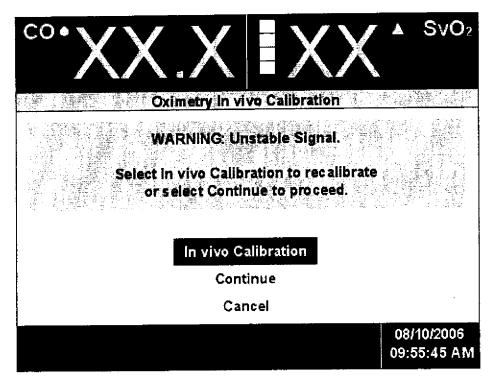


Figure 7-12 Oximetry In vivo Calibration Signal Error

1. If a Wall Artifact or Wedge Detected, or Unstable Signal message appears, attempt to troubleshoot the problem as instructed in Chapter 12: *Troubleshooting*, and select *In vivo* Calibration to restart the Baseline Setup.

OR

Select Continue, which tells the Vigileo monitor to continue the Draw operation.

OR

Select Cancel to return to the beginning of the oximetry calibration process.

If baseline calibration is successful, the message in the menu changes to show instructions for the next step.

7. F



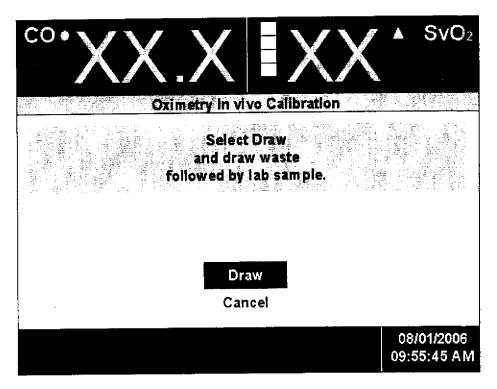


Figure 7-13 Oximetry In vivo Calibration Draw Screen

2. Press the navigation knob and then draw the blood sample.

The display changes to show the draw time and the values of parameters $ScvO_2/SvO_2$ and HGB at the draw time, as shown in the following screen illustration.

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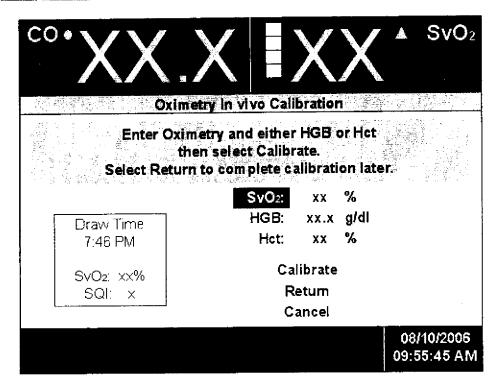


Figure 7-14 Oximetry In vivo Calibration Data Entry

Table 7-3 In vivo Calibration Data Options

Option	Description	Value Ranges
SvO ₂ or ScvO ₂	Enter an ScvO ₂ /SvO ₂ value to use for calibration	10.0 to 99.0 by 0.1
HGB (g/dl)	Enter an HGB value to use for calibration	4.0 to 20.0 by 0.1
HGB (mmol/l)		2.5 to 12.4 by 0.1
Hct (%)	Enter an Hct value to use for calibration	12 to 60 by 1
Calibrate	Start the optical module update process	None
Return	Stop ScvO ₂ /SvO ₂ calibration and suspend monitoring.	None
Cancel	Discard baseline data and ScvO ₂ /SvO ₂ / HGB/Hct values and abort the calibration process.	None

- 3. Draw the waste blood sample slowly from the distal lumen.
- 4. Draw the laboratory blood sample slowly (2 ml (cc) over 30 seconds).
- 5. Send the blood sample for measured analysis by co-oximeter.



NOTE

While waiting for the HGB/Hct and oximetry laboratory values, other modes may be accessed by selecting **Return**. To return to the *In vivo* Calibration screen, select the Oximetry Frame and then select *In vivo* Calibration.

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6. Upon receipt of the lab values from the drawn sample, use the navigation knob to enter the oximetry value and either the HGB or Hct.



NOTE

Upon entry of either the HGB or Hct value, the *Vigileo* monitor will automatically calculate the other value. If both HGB and Hct values are selected, the monitor will accept the last value entered.

7. After the values are entered, *rotate* the navigation knob to select **Calibrate**. This action initiates the calibration of the Optical Module.

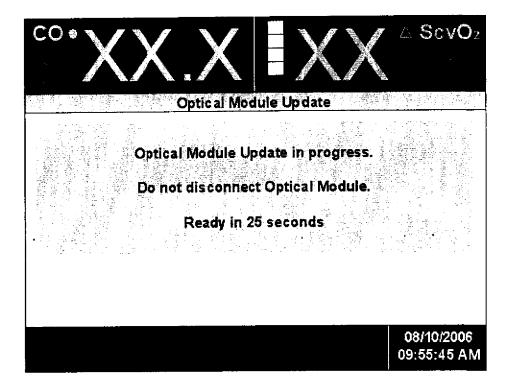


Figure 7-15 Optical Module Update Screen

At the end of the 25 second countdown, the Calibration menu is removed from the screen and the Oximetry Frame ivient is displayed.

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7.8.1 Recall OM Data

In the event that a patient needs to be transported while oximetry is being monitored, patient data (e.g., height, weight, and BSA) and system calibration information can be transferred with the patient via the Optical Module, eliminating the need to recalibrate the monitor.

1. With the catheter connected to the Optical Module, unplug the Optical Module cable from the *Vigileo* monitor and transport it with the patient. The catheter should not be disconnected from the Optical Module.



NOTE

The monitor does not need to be transferred with the patient. Any Edwards monitor, except the SAT-1, that supports the Optical Module can be used for oximetry measurement.

- **2.** If the Optical Module is being connected to another *Vigileo* monitor, make sure that previous patient data is cleared from the monitor.
- **3.** Once the patient has been transferred, reconnect the Optical Module cable to the *Vigileo* monitor.
- **4.** Rotate the navigation knob to highlight the Oximetry Frame.
- 5. Press the knob.
- 6. Select Recall OM Data.
- 7. The calibration data in the Optical Module will be displayed.

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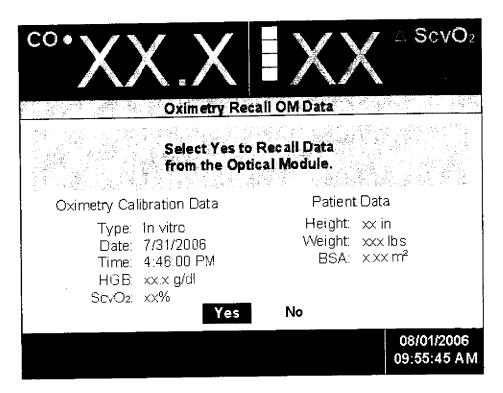


Figure 7-16 Recall OM Data

8. If the Optical Module data is less than 24 hours old, confirmation instructions and a Yes/No confirmation is displayed.

Select Yes to start oximetry monitoring using the recalled calibration information.

OR

Select No and perform an In vivo calibration.



NOTE

Keep the data and time of all *Vigileo* monitors current. If the date and/or time of the *Vigileo* monitor being transported "from" differs from the *Vigileo* monitor being transported "to," then the 24 hour test may not work properly.

If the Optical Module data is more than 24 hours old, the Optical Module data cannot be recalled and a new calibration must be performed.

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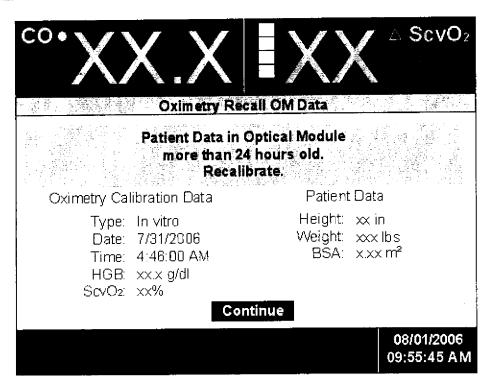


Figure 7-17 Recall OM Data

9. Select **Continue** to exit the calibration menu, and select *In vivo* **Calibration** to recalibrate the Optical Module.



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NOTE

If the system is to be recalibrated, a 10 minute warm up period for the Optical Module may be required.

10. To review patient data that was transported with the Optical Module, select the **Patient Data** option from the CO Frame Menu.

7.8.2 HGB Update Screen

The update function can be used usily if a previous calibration has been performed, or if the calibration data has been recalled from the Optical Module.

- 1. *Rotate* the navigation knob until the Oximetry Frame is highlighted and then *press* the knob. The Oximetry menu displays.
- 2. *Rotate* the navigation knob until **HGB Update** is highlighted and then *press* the knob. The following menu displays:

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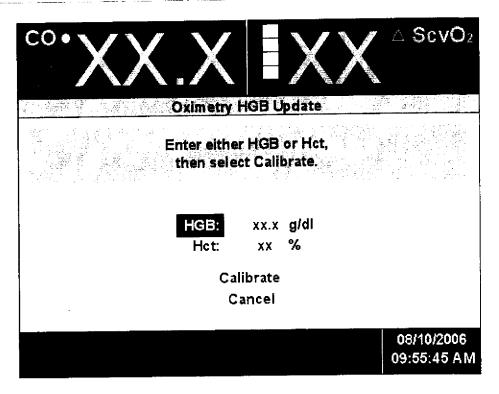


Figure 7-18 HGB Update Screen

- **3.** You can use the displayed values or enter new values. *Rotate* the navigation knob to highlight an option and then *press* the knob.
- 4. To change the HGB value, rotate the navigation knob and select HGB.
- 5. *Rotate* the knob clockwise to increase the HGB value, or *rotate* the knob counterclockwise to decrease the value.
- **6.** *Press* the knob to lock in the value. The Het value will be automatically calculated and displayed.
- 7. To change the Hct value, rotate the navigation knob and select Hct.
- **8**. *Rotate* the knob clockwise to increase the Hct value, or *rotate the* knob counterclockwise to decrease the value.
- 9. Press the knob to lock in the value. The HGB value will be automatically calculated and displayed
- **10**. To recalibrate the Optical Module, select **Calibrate**. The following screen will display.



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NOTE

To achieve optimal accuracy, it is recommended that the entered HGB and Hct values be updated when there is a physiologic change of 6% or greater in Hct or of 1.8 g/dl (1.1 mmol/l) or greater in HGB. A change in hemoglobin may also affect SQI. Use the HGB Update function to remedy signal quality problems.

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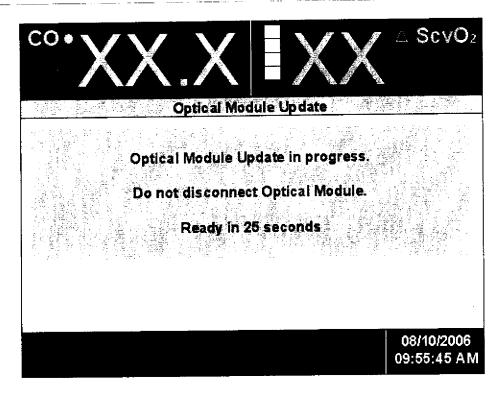


Figure 7-19 Optical Module Update Screen

11. To stop the calibration process, select **Cancel** from the Oximetry HGB Update screen. Any HGB or Hct value that was entered will be discarded and the HGB Update Screen will close.

7.8.3 Optical Reset

When the SQI level is continuously high, an optical reset may stabilize the signal quality. An optical reset should be performed only after attempting other actions to resolve the high SQI as defined in Chapter 12: *Troubleshooting*.

- 1. *Rotate* the navigation knob until the Oximetry Frame is highlighted and then *press* the knob. The Oximetry menu displays.
- 2. Rotate the navigation knob until Sprient Reser is highlighted and then press the knob. The following screen displays.

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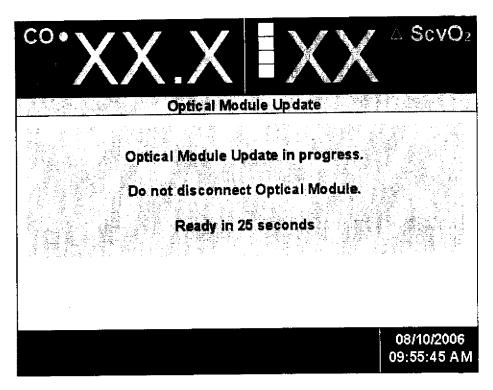


Figure 7-20 Optical Module Update Screen



NOTE

The monitor will not permit an Optical Reset prior to performing a calibration or prior to recalling calibration from the Optical Module.

7.8.4 New Catheter

When a new catheter is to be used for a patient, the system must be recalibrated.

- 1. Rotate the navigation knob until the Oximetry Frame is highlighted and then press the knob. The Oximetry menu displays.
- 2. Rotate the navigation knob until New Catheter is highlighted and then press the knob.
- **3.** The operator will be asked to confirm that a new catheter is being connected. To confirm the new catheter, select **Yes**. The *In vitro* Calibration option will be available for selection and calibration of the new catheter.

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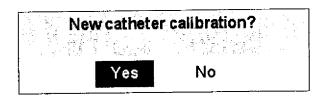


Figure 7-21 New Catheter Calibration Confirmation

Selecting the **No** option indicates that a new catheter is not being connected and the monitor will continue oximetry monitoring.

4. Rotate the navigation knob until the Oximetry Frame is highlighted and then press the knob. The Oximetry menu displays.

7.9 Signal Quality Index (SQI)

SQI is a reflection of the signal quality based on the catheter condition and positioning within the vessel. The SQI bar boxes fill based on the level of oximetry signal quality with the level number displayed in the lower bar box.



The SQI level is updated every two seconds after oximetry calibration is complete and can display four signal levels:

, Table 7-4 Signal Quality index Levels

Level	Color	Description
1 Normal	Green	All aspects of the signal are optimal
2 Intermediate	Yellow	Indicates a moderately compromised signal
3 Poor	Red	Poor Indicates poor signal quality
4 Unacceptable	Red	Indicates severe problem with one or more aspects of signal quality

Signal quality may be compromised by the following:

- Pulsatility (for example, the catheter tip is wedged)
- Signal Intensity (for example, the catheter is kinked, a blood clot, hemodilution)
- Intermittent vessel wall contact by the catheter

Signal Quality is displayed during *In vivo* Calibration and HGB Update functions. It is recommended that calibrations be performed only when the SQI is at a level of 1 or 2. When SQI is 3 or 4, see Chapter 12: Troubleshooting on page 12-1 to determine and resolve the issue.



NOTE

The SQI signal is sometimes affected by the presence of electrosurgical units. Attempt to distance electrocautery equipment and cables from the *Vigileo* monitor and plug the power cords into separate AC circuits if possible. If signal quality problems persist, call your local Edwards Representative for assistance.

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Chapter 8 Monitor Status and Configuration

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8.1 Overview

The Status Frame displays the highest priority, active CO and Oximetry status messages. If there is only one status message, it is displayed continuously. If there are both CO and Oximetry status messages, the messages display alternately.

8.1.1 Selecting the Status Frame

1. *Rotate* the navigation knob until the Status Frame is highlighted and then *press* the knob.

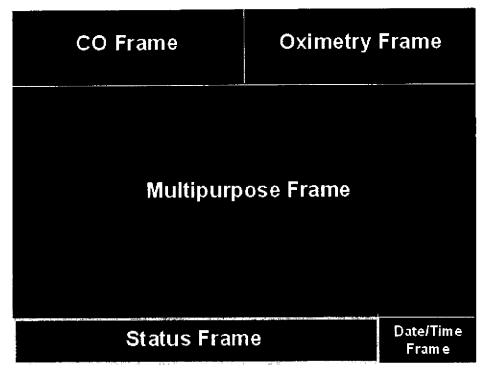


Figure 8-1 Main Monitoring Screen with Status Frame Selected

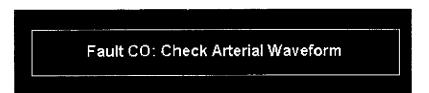


Figure 8-2 Status Frame Message

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8.2 Status Menu

The Status Frame Menu allows you to select additional screens and menus that will display monitor status and allow you to set up monitor features. The Status Frame Menu is displayed when you select the Status Frame as well as when you select the **Return** option in the following screens:

- Patient Data Menu
- Display Messages Screen
- Display Setup Menu
- Serial Port Setup Menu
- Analog In and Analog Out Setup Menus

The menu displays until you exit the screen or until two minutes have passed with no activity.

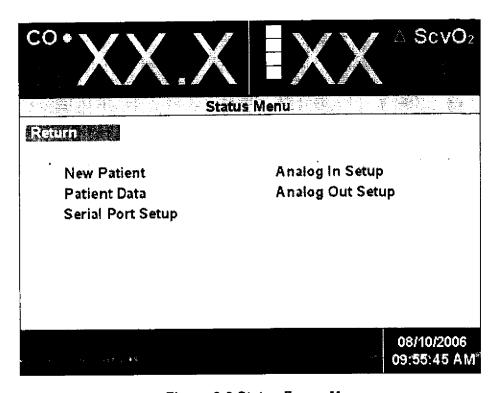


Figure 8-3 Status Frame Menu

- 1. To configure an option, *rotate* the navigation knob until the option is highlighted and then *press* the knob.
- 2. Rotate the knob to scroll through the available choices and then press the knob to make your selection.
- **3.** Repeat Step 2 to configure other parameters.
- 4. When you are done, *rotate* the knob to highlight **Return** and then *press* the knob.

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Table 8-1 Status Frame Menu Options

Option	Description
New Patient	Displays a confirmation window. If "No" is selected, the confirmation window is closed. If "Yes" is selected, the confirmation window is closed, all patient data is cleared, the alarm limits for CO/CI and ScvO ₂ /SvO ₂ are set to default values, and all alarms are enabled.
	All affected frames are updated.
Patient Data	Displays the Patient Data Menu.
Serial Port Setup	Display the Serial Port Setup Menu.
Analog In Setup	Display the Analog In Setup Menu.
Analog Out Setup	Display the Analog Out Setup Menu.
Return	Display the previously active Multipurpose Frame Screen.

8.2.1 New Patient

When you select New Patient, the following confirmation screen will display.

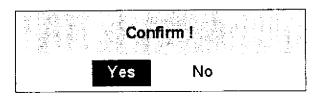


Figure 8-4 Status Frame Message

- 1. If this is a new patient, *rotate* the navigation knob to highlight **Yes** and *press* the knob.
 - All patient data is cleared, the alarm limits for CO/CI and ScvO₂/SvO₂ are set to their default values, and all alarms are enabled. All affected frames are updated.
- 2. If this is not a new patient, *rotate* the navigation knob to highlight **No** and *press* the knob. The window closes and no data is reset.

8.2.2 Patient Data Menu

The Patient Data Menu displayed when the Patient Data option is selected in the Status Frame Menu.

The menu displays until you select the **Return** option or until two minutes passes with no activity. If the screen closes due to inactivity, any data entries are lost.

- 1. *Rotate* the navigation knob until the Status Frame is highlighted and then *press* the knob.
- 2. Rotate the navigation knob to highlight Patient Data and then press the knob.

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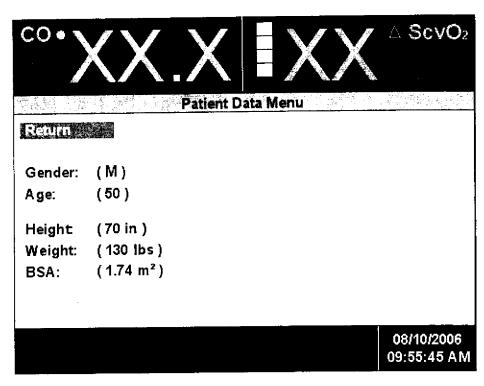


Figure 8-5 Patient Data Menu

- 3. Rotate the navigation knob to select the desired field to change.
- 4. Rotate the navigation knob to select the value of the field and then press the knob.
- 5. When finished, rotate the navigation knob to Return and then press the knob.

Table 8-2 Patient Data Menu Options

Parameter	Options	Description
Gender	М	Male
	F	Female
Age -	2 to 120 in increments of 1	Patient's age
Weight	2 to 880 lbs by 1 1.0 to 400 0 Kg by 0.5	Patient's weight in pounds or kilograms.
Height	12 to 98 in by 1 30 to 250 cm by 1	Patient's height in inches or centimeters.
BSA	0.08 to 5.02 m ² by 0.01	When the BSA value field changes, the Height and Weight fields are automatically cleared.

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8.2.3 Serial Port Setup Menu

Use the Serial Port Setup Menu to configure the serial port for bidirectional digital data transfer.

The screen displays until you select the **Return** option or until two minutes passes with no activity. If the screen closes due to inactivity, any data entries are lost.

- 1. Rotate the navigation knob until the Status Frame is highlighted and then press the knob.
- 2. Rotate the navigation knob to highlight Serial Port Setup and then press the knob.

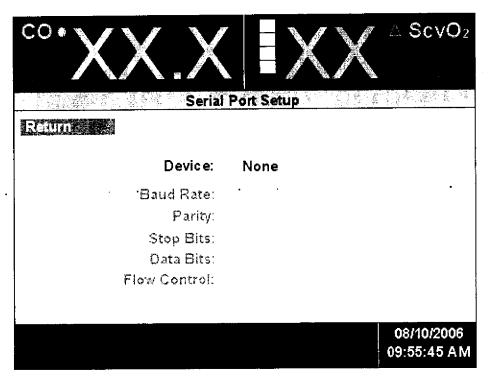


Figure 8-6 Serial Port Setup

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Parameter options are dependent on other selections. If an option is gray, it is not available.

- 1. Rotate the navigation knob to select the field you want to change.
- 2. Rotate the navigation knob to select the value of the field and then press the knob.
- 3. When finished, rotate the navigation knob to Return and then press the knob.

Table 8-3 Serial Port Setup Options

Device Choices	Port Options	Selection Choices	Defaults
DataLog	Baud Rate	None	57600
 	Parity	None	None
	Stop Bits	None	1
-	Data Bits	None	2
	Flow Control	None	None
None	Baud Rate	None	(Blank)
(Factory Default)	Parity	None	(Blank)
	Stop Bits	None	(Blank)
	Data Bits	None	(Blank)
	Flow Control	None	(Blank)

8.2.4 Analog In Setup Menu

Use the Analog In Setup Menu to configure the Analog Input port.

The screen displays until you select the **Return** option or until two minutes passes with no activity. If the screen closes due to inactivity, any data entries are lost.

- 1. *Rotate* the navigation knob until the Status Frame is highlighted and then *press* the knob.
- 2. Rotate the navigation knob to highlight Analog In Setup and then press the knob.
- 3. Rotate the navigation knob to highlight Parameter and then press the knob.
- **4.** Set the parameter to **CVP** and then *press* the knob.
- 5. Rotate the navigation knob to highlight Voltage Range and then press the knob
- 6. Select the voltage range for the **Analog Input Port** and then *press* the knob.
- 7. Rotate the navigation knob to highlight Full Scale Range.
- **8.** Select the greatest CVP value and then *press* the knob. The full scale range is between 80 to 100 mmHg (10.7 to 13.3 kPa).

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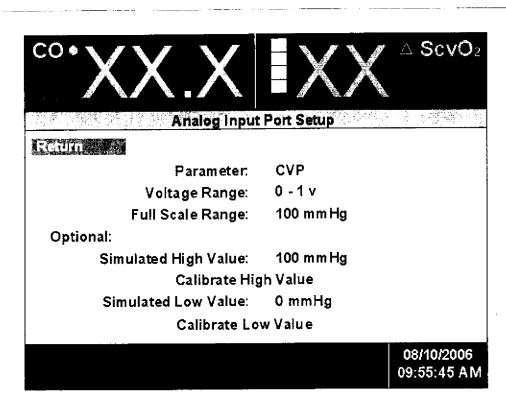


Figure 8-7 Analog Input Port Setup Screen

Table 8-4 Analog Input Port Configuration Options, Choices, and Defaults

Parameter	Parameter Options	Selection Choices	Defaults
CVP Voltage Range		0 to 1 v	0 to 1 v
		0 to 5v	
		0 to 10v	
	Full Scale Range	80 to 100 mmHg by 1 mmHg	100 mmHg
		10.7 to 13.3 kPa by 0.1 kPa	13.3 kPa
	Simulated High Value	50 to 100 mmHg by 1 mmHg	100 mmHg
		6.7 to 13.3 kPa by 0.1 kPa	13.3 k₽a
	Simulated Low Value	0 to 10 mmHg by 1 mmHg	0 mmHg
		0.0 to 1.3 kPa by 0.1 kPa	0.0 kPa
None	Voltage Range	None	(Blank)
(Factory	Full Scale Range	None	(Blank)
Default)	Simulated High Value	None	(Blank)
	Simulated Low Value	None	(Blank)

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You can calibrate the incoming analog signal being output by the attached analog output device to the Simulated High Value using the Calibrate High Value option and to the Simulated Low Value using the Calibrate Low Value option. The screen displays until you select the Return option.

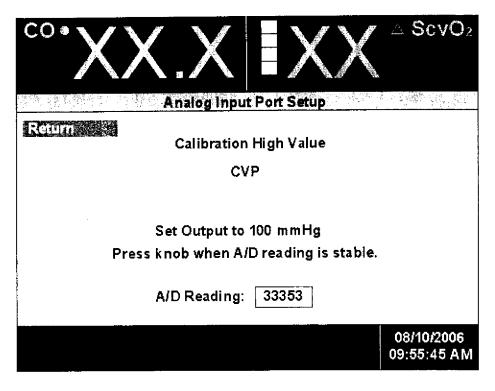


Figure 8-8 Analog Input Port Setup - Calibrate High Value

The A/D Reading field displays the number of A/D counts currently being read at the A/D Converter. When the navigation knob is pressed, the value in the A/D Reading field is locked in as the upper value for the calibration algorithm.

The Analog Input Port Calibrate Low Value Screen allows you to calibrate the incoming analog signal being output by the attached analog output device to the Simulated Low Value.

The screen displays until you select **Return**.

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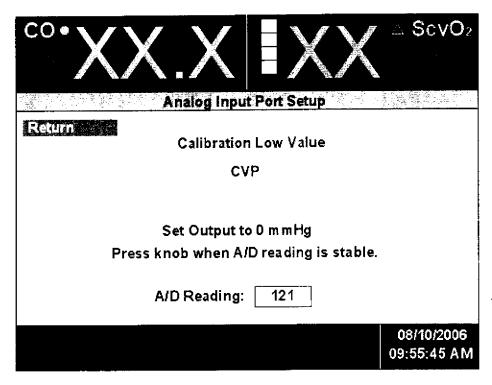


Figure 8-9 Analog Input Port Setup - Calibrate Low Value

The A/D Reading field displays the number of A/D counts currently being read at the A/D Converter. When the navigation knob is pressed, the value in the A/D Reading field is locked in as the lower value for the calibration algorithm.



CAUTION

The accuracy of continuous SVR depends upon the quality and accuracy of the CVP data transmitted from the external monitors. Since CVP analog signal quality from the external monitor cannot be validated by the *Vigileo* Monitor, actual values and the values (including all derived parameters) displayed by the monitor may not be consistent. Refer to the external input device operator's manual for detailed information regarding accuracy, calibration, and other variables which may impact the analog output signal from the external monitor.

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8.2.5 Analog Out Setup Menu

Use the Analog Out Setup Menu to configure the analog output port.

The screen displays until you select the **Return** option or until two minutes passes with no activity. If the screen closes due to inactivity, any data entries are lost.

- 1. *Rotate* the navigation knob until the Status Frame is highlighted and then *press* the knob
- 2. Rotate the navigation knob to highlight Analog Out Setup and then press the knob.

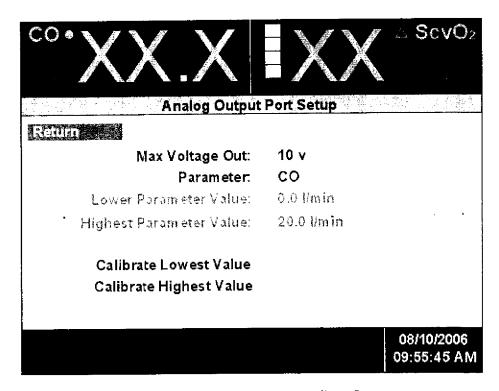


Figure 8-10 Analog Output Port Setup

- 3. Rotate the navigation knob to highlight Max Voltage Out and then press the knob.
- **4.** Select the maximum voltage to output to the analog output port. The choices are 10 v or 1 v.
- **5**. *Press* the navigation knob to save your selection.
- **6**. *Rotate* the navigation knob to highlight **Parameter** and then *press* the knob.
- 7. Select the parameter you want configured to the analog output port and then *press* the knob.
- **8.** The calibration values are shown in the Lowest Parameter Value and Highest Parameter Value fields.

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8.2.6 Calibrate Analog Device

You can calibrate a device that is receiving analog data from the *Vigileo* Monitor.

The screen displays until you select the Return option.

- 1. Rotate the navigation knob to highlight Calibrate Highest Value and press the knob. A 1 v or 10 v reference level displays, depending on the current Max Voltage Out selection.
- 2. Rotate the knob to highlight Calibrate Lowest Value and press the knob. A 0 v reference level is sent out the analog out port.

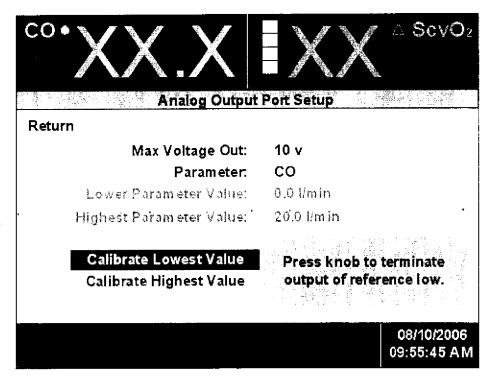


Figure 8-11 Analog Output Port Calibrate Lowest Value

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Chapter 9 Date and Time

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9.1 Overview

The current Time and Date are displayed at the lower right portion of the screen in the Date/Time Frame, with the default format based on the language selected. You can set the time and date and select the display format from the Time and Date Menu.

The CO, Oximetry, and Status Frames update normally while you are making changes in the date or time formats.

9.1.1 Display the Time and Date Menu

1. Rotate the navigation knob until the Date/Time Frame is highlighted.

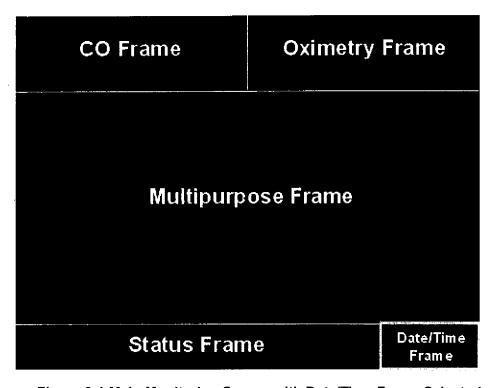


Figure 9-1 Main Monitoring Screen with Date/Time Frame Selected



Figure 9-2 Date/Time Frame

2. Press the knob to display the Time and Date Menu.

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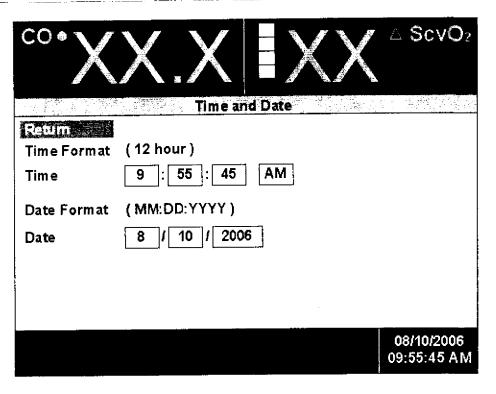


Figure 9-3 Time and Date Menu

9.2 Selecting the Time and Date Display Format

The menu displays until you select **Return** or until two minutes passes with no activity. If the menu expires due to inactivity, any selections in progress are lost.

- **1.** *Rotate* the navigation knob to highlight the Date/Time Frame and *press* the knob. The Time and Date menu displays.
- 2. Rotate the navigation knob to highlight Time Format.
- 3. Press the navigation knob. The highlighting shifts to the value field.
- **4.** Rotate the navigation knob to change the selection.
- **5.** *Press* the navigation knob to confirm your selection. The selected format will display next to **Time Format** and the Date/Time Frame will be updated to the selected format.
- 6. Rotate the navigation knob to highlight Date Format.
- 7. Press the navigation knob. The highlighting shifts to the value field.

To set the date format to 12/4/2003, select MM:DD:YYYY. To set the date format to 4.12.2003, select DD:MM:YYYY.

- 8. Rotate the navigation knob to select your preference.
- **9**. *Press* the navigation knob to confirm your selection.

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9.2.1 Setting the Current Date

- 1. Rotate the navigation knob to highlight Date.
- 2. Press the navigation knob. The first Date field is highlighted.
- 3. *Rotate* the navigation knob to highlight the date field you want to set and then *press* the navigation knob.
- **4.** *Rotate* the navigation knob clockwise to advance the date or counterclockwise to decrease the date value.
- 5. Press the navigation knob to confirm your selection.
- 6. Repeat steps 3 through 5 for the remaining fields.
- 7. To confirm the date setting and exit the menu, select **Return** and then *press* the navigation knob. The Time/Date Frame will be updated to the new date.

9.2.2 Setting the Current Time

- 1. Rotate the navigation knob to highlight Time.
- 2. Press the navigation knob. The first Time field becomes highlighed.
- 3. Rotate the navigation knob to highlight the time field you want to set.
- 4. Press the navigation knob.
- 5. Rotate the navigation knob clockwise to advance the time or counter-clockwise to decrease the time value.
- 6. Press the navigation knob to confirm your selection.
- 7. Repeat steps 3 through 6 for the remaining fields, including AM and PM if you are using a 12-hour clock.
- 8. To confirm the time setting and exit the menu, select **Return** and then *press* the navigation knob. The Time/Date Frame will be updated to the new time.

Chapter 10 Reports

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1.3 Printing a Report	

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10.1 Overview

A grayscale bitmap of the screen can be sent to a printer via the USB Port. The report configures itself to the paper width. If the screen contents are wider than the paper, the report will print in sections.

While printing, a message displays in the Status Frame "Printing in Progress."



WARNING

All IEC/EN 60950 equipment, including printers, must be positioned no closer than 1.5 meters to the patient's bed.

10.2 Supported USB Devices

The USB Port supports the screen-printing function to selected printers. Printers must have an ITE Class II power supply. Please contact your local Edwards Lifesciences Representative for approved printers and appropriate USB cables.

10.3 Printing a Report

- 1. Connect a USB cable to the port at the rear of the Vigileo monitor.
- 2. Connect the other end of the USB cable to a printer.
- 3. Make sure paper is loaded.
- 4. Press the Printer button on the monitor keypad.





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Chapter 11 Data Display

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11.1 Overview

In addition to displaying the menus used to set up monitoring operations, the Multipurpose Frame is used to display and update the values of six selectable parameters.

The CO, Oximetry, Status, and Date/Time Frames update normally while the All Data Screen or subordinate menus are displayed.

$\overline{\Lambda}$	CAUTION
	Do not disconnect the optical module while calibration and patient data are being transferred from the Vigileo monitor.
\wedge	CAUTION
	In order to avoid data corruption, always disconnect the patient cable and
	optical module from the Vigileo monitor before using a defibrillator.

11.2 Selecting the Multipurpose Frame

1. *Rotate* the navigation knob until the Multipurpose Frame is outlined in yellow and then *press* the navigation knob.

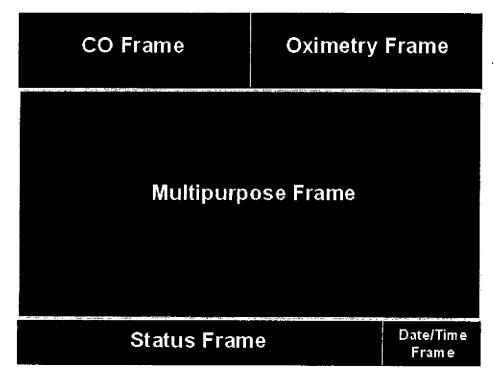


Figure 11-1 Main Monitoring Screen with Multipurpose Frame Selected

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11.3 All Data

The All Data Screen continuously displays and updates the values of six selectable parameters.

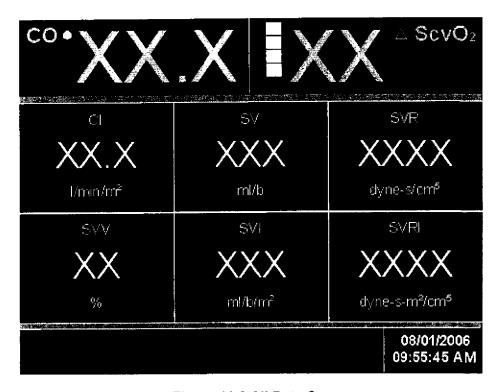


Figure 11-2 All Data Screen

11.3.1 All Data Menu

The All Data Menu lets you select the parameters that will display on the All Data screen. The menu displays until you select the **Return** option or until two minutes have passed with no activity. If the screen expires due to inactivity, any selections are lost.

A filled in box next to the parameter indicates the parameter is selected for display. An outline box indicates the parameter will not be displayed. Each parameter toggles between select/deselect. In the figure shown on the next page, SVI is not selected for display.

- 1. Rotate the navigation knob until the Multipurpose Frame is outlined in yellow and then press the navigation knob.
- **2.** *Rotate* the navigation knob until the All Data Screen displays in the Multipurpose Frame.

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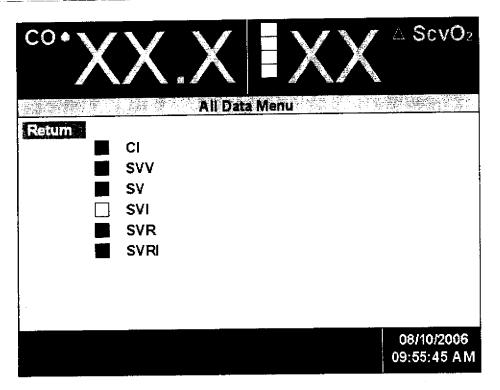


Figure 11-3 All Data Menu

- 3. Rotate the navigation knob to highlight the parameter you want to select or deselect and then press the knob.
- **4.** Repeat the previous step to select each data type you want included in the All Data display.
- 5. Rotate the navigation knob to highlight **Return** when you have completed making your parameter display choices.

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Chapter 12 Troubleshooting

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12.1 Overview

Use the information in this chapter to determine the cause and remedy for error messages displayed in the Status Frame. The messages are grouped according to the monitoring function they relate to.

12.1.1 Faults

Faults are the highest priority error (excluding shutdowns). A repeating series of tones is sounded when monitoring of a continuous trended parameter is stopped by the fault.

If monitoring is not stopped or the monitoring is already stopped, a tone is not sounded.

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12.2 CO/CI Messages and Troubleshooting

Table 12-1 CO/CI Faults

Fault Message	Possible Cause	Suggested Action
Check Pressure Cable Connections	Cable connections not detected APCO cable malfunction	Verify APCO cable and catheter Disposable Pressure Transducer connections.
Cable Connections	Ar CO cable maliculation	Disconnect Disposable Pressure Transducer and check for bent/missing pins.
		Change APCO cable.
Check Arterial Waveform	Arterial waveform is inadequate to measure CO accurately.	Check the arterial waveform for noise, motion artifacts, or over-damping.
	Pressure has been bad too long.	Check the arterial line and connections.
		Check cable connections.
Arterial Pressure Not Zeroed	The arterial pressure signal must be zeroed prior to CO monitoring.	Choose "Zero Arterial Pressure" from the CO menu.
Signal Processor		Disconnect and re-connect APCO cable.
Ü		Power monitor off and on to restore system.
		If problem persists, contact Edwards Technical Support.

Table 12-2 CO/CI Alerts

CO/CI Alert Messages	Possible Cause	Suggested Action
Unstable Pressure Signal	Arferial waveform is becoming inadequate to measure CO	Check the arterial waveform for noise, motion artifacts, or over-damping.
	accurately.	Check the arterial line and connections.
		Check cable connections.
Pulse Pressure Low	Integrity of pressure monitoring system is compromised.	Check the arterial waveform for noise, motion, artifacts, or over-damping.
	Incorrect zeroing of Arterial Pressure.	Check the arterial line and connections. Check cable connections.
	Patient Condition results in a low pulse pressure.	Re-zero the arterial pressure.

Table 12-3 CO/CI General Troubleshooting

CO/CI Alert Messages	Possible Cause	Suggested Action
CI > CO	Incorrect patient BSA	Verify units of measure and values for
	BSA <1	patient's height and weight

12.3 Oximetry Messages and Troubleshooting

Table 12-4 Oximetry Faults

Fault Message	Possible Cause(s)	Suggested Action
OM Temperature	Optical module malfunction	Change optical module and recalibrate.
OM Memory	Optical module memory malfunction	Disconnect and then reconnect the cable.
		Change optical module and recalibrate.

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Table 12-4 Oximetry Faults

Fault Message	Possible Cause(s)	Suggested Action
Light Range	Poor optical module/catheter connection	Verify secure optical module/catheter connection.
	Debris or film obstructing optical module/catheter connector lens	Clean optical module/catheter connectors with70% isopropyl alcohol and swab, let air dry and recalibrate.
	Optical module malfunction Catheter kinked or damaged	Change optical module and recalibrate.
	Cathelet killked of damaged	Replace catheter if damage is suspected and recalibrate
Value Out of Range	Incorrectly entered SvO ₂ /ScvO ₂ ,	Verify correctly entered SvO ₂ /ScvO ₂ , HGB
	HGB or Hct values	and Hct values
	Incorrect HGB units of measure	Verify correct HGB unit of measure
	Calculated SvO ₂ /ScvO ₂ value is	Obtain updated SvO ₂ /ScvO ₂ lab values and
	outside of the 0-99% range	recalibrate
Red/IR Transmit	Debris or film obstructing optical module/catheter connector lens	Clean module/catheter connectors with 70% isopropyl alcohol and swab, let air dry
	Optical module malfunction	and recalibrate
		Change optical module and recalibrate
OM Disconnected	Optical module connection at monitor not detected	Verify secure optical module/catheter connection
	Bent or missing optical module connector pins	Check optical module cable connector for bent/missing pins

Table 12-5 Oximetry Alerts

Alert Message	Possible Cause(s)	Suggested Action
SQI = 4	Low blood flow at catheter tip or catheter tip against vessel wall Significant change in HGB/Hct values Catheter tip clotted Catheter kinked or damaged	Verify proper catheter position. Confirm wedge pressure balloon inflation volume of 1.25-1.50 ml for PAC Confirm appropriate catheter placement for patient's height, weight and insertion site Consider chest x-ray for evaluation of proper placement Aspirate then flush distal lumen per hospital protocol Update HGB/Hct values using Update function Check catheter for kinking and recalibrate Replace catheter if damage is suspected and recalibrate

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Table 12-6 Oximetry Warnings

Warning Message	Possible Cause	Suggested Action
In Vitro Calibration Error	Poor optical module and catheter SvO ₂ /ScvO ₂ connection	Verify secure optical module/catheter connection
	Calibration cup wet Catheter kinked or damaged	Straighten any visible kinks; replace catheter if damage is suspected
	Optical module malfunction Catheter tip is not in catheter	Change optical module and recalibrate Verify catheter tip is securely seated in
	package calibration cup	calibration cup Perform in vivo calibration
Unstable Signal	Changing SvO ₂ /ScvO ₂ , HGB/Hct, or unusual hemodynamic values	Stabilize patient per hospital protocol and perform in vivo calibration
Wall Artifact or Wedge Detected	Low blood flow at catheter tip Catheter tip clotted	Aspirate then flush distal lumen per hospital protocol
	Catheter tip wedged in vessel or against vessel wall	Verify proper catheter position in the pulmonary artery.
		Confirm wedge pressure balloon inflation volume of 1.25-1.50 ml for PAC
		Confirm appropriate catheter placement for patient's height, weight and insertion site
		Consider chest x-ray for evaluation of proper placement
		Perform in vivo calibration

Table 12-7 Oximetry General Troubleshooting

General Messages	Possible Cause	Suggested Action	
Optical Module Not Calibrated - Select Oximetry Frame to calibrate	Optical module has not been calibrated (in vivo or in vitro) Recall OM Data function has not been performed	Perform in vivo or in vitro calibration Perform Recall OM Data function if module was previously calibrated Change optical module and recalibrate	
	Optical module malfunction		
Patient Data in Optical Module more than 24 hours old - Recalibrate	Last optical module calibration >24 hours old Date and time on the Vigileo monitor at facility are modified.	Perform in vivo calibration Synchronize date and time on all monitors at facility	

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12.4 SVR/SVRI Alerts and Troubleshooting

Table 12-8 SVR/SVRI Alerts

Alert Message	Possible Cause	Suggested Action
SVR: Slaved-In Pressures Signal Loss	Vigileo analog input port not configured to accept CVP Analog input interface cable connections not detected Inaccurate input signal External monitor malfunction	Verify correct voltage range and low/high voltage values on the Vigileo monitor for external monitor Verify cable connection between the Vigileo monitor and bedside monitor is secure Verify correct height/weight entries and units of measure for patient's BSA Check for signal at external monitor's analog output device Change external device module, if used

Table 12-9 SVR/SVRI General Troubleshooting

CO/CI Alert Messages	Possible Cause	Suggested Action
SVR > SVRI	Incorrect patient BSA <1	Verify units of measure and values for patient's height and weight
CVP ≠ External Monitor	Vigileo monitor configured incorrectly Inaccurate input signal External monitor malfunction	Verify correct voltage range and low/high voltage values on Vigileo monitor for external monitor Confirm correct units of measure for analog input port voltage values (mmHg or kPa) Verify correct height/weight entries and units of measure for patient's BSA Check for signal at external monitor's analog output device Change analog input interface cable Change external device module, if used Clear asterisk (*) from Cardiac Profile screen for CVP if slaving from an external

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Appendix A Specifications

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A-1 Overview

The *Vigileo* monitor measures arterial pressure cardiac output (APCO) and oximetry (oxygen saturation, ScvO₂/SvO₂) when used with appropriate Edwards Continuous Cardiac Output and Oximetry Catheters.

Appendix A includes summaries of the following:

- Physical and Mechanical Specifications
- Environmental Specifications
- Technical Specifications
- Base, Volumetric and SvO₂ Parameters
- Patient Data Profiles
- · Accessories for use with the Vigileo monitor

A-2 Physical and Mechanical Specifications

Table A-1 Physical and Mechanical Specifications

Weight		6 lbs. 2.73 Kg
Dimensions		
	Height	7.3 inches
,	Width	10.7 inches
	Depth	8.4 inches
TFT Display	Active Area	
Trend Display	Time Axis	30 minutes to 24 hours (for Trend Graph) 1 minute to 60 minutes (for Tabular Trend)
	Configuration	Graphical Trend Data Tabular Trend Data (up to five non-indexed parameters) All Data (up to six parameters)
	Parameters	Four fixed frames (CO, Oximetry, Status, Date/ Time One multipurpose frame

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Table A-2 Environmental Specifications

Parameter	Value
Operating temperature without Optical Module	0 to 50°C
Operating temperature with Optical Module	10 to 37°C
Storage Temperature	-25 to 70°C
Relative Humidity, Operating and Storage	10% to 95%, non-condensing
Operating Atmospheric Pressure	696 to 1013 hPa

Table A-3 Technical Specifications

Input/Output	Analog Inputs	Selectable full-scale:
		0 to 1V
		0 to 5V
		0 to 10V
		>100 kΩ input impedance;
		1/8 in. stereo jack;
		Bandwidth = 5 Hz;
į		Resolution: 12 bits ±1 LSB of full scale
	Analog Outputs (1)	Selectable full-scale range; 0 to 1V, 0 to 10V;
		Bandwidth = 10 Hz;
		Resolution = 8 bits;
		Absolute Accuracy = ±2.5%;
;		Linearity = ±1%;
		1/8 in. stereo jack
	Digital I/O (2)	RS232 programmable serial ports; Maximum data rate = 19.2 kilobaud
	Keypad	Six (6) front-panel push buttons:
i		1 power ON/OFF
		Five (5) monitoring selections
	USB Port	One V1.1-compatible type A connector
Electrical	Voltage	100 to 240 Vac
		50/60 Hz
	Power Consumption	1 A maximum
	Fuse	Two 1-amp, 250-volt, Time Lag, Low Breaking Capacitance, 5x20 mm

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A-3 Parameters

Table A-4 Base Parameters

Parameter	Specification	
APCO	Range	1 to 20 l/min
Arterial Pressure Cardiac Output	Reproducibility ¹	±6% or 0.1 l/min, whichever is greater
	Update Rate	20 seconds

Table A-5 Volumetric Parameters

Parameter	Specification	and the same of th	
PR	Update Rate	Averaged over 20 seconds	

Table A-6 SvO₂ Parameters

Parameter	Specification	
SvO ₂	Range	0 to 99%
Oximetry (Oxygen Saturation)	Precision ²	±2% at 30 to 99%
	Update Rate	2 seconds
² Precision was tested under labor	pratory conditions.	

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A-4 Accessories



WARNING

Connect only accessories that have been qualified as part of the $\emph{Vigileo}$ monitoring system.

Table A-7 Vigileo Monitor Accessories

Accessory	Model
Edwards Oximetry Catheters	*
Edwards Dual Disposable Pressure Transducers	*
Power Cord *	*
Operator's Manual	*
Reusable APCO Cable	APCO9
Optical Module	Model OM2 or OM2E†
Printer	USB, with ITE Class II supply
Printer Interface Cable	USB compatible
Pressure Slave Cable	Edwards 70AN series **
Adapter Plate	*MHADPLT

^{*} Please contact your Edwards representative for model and ordering information.

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[†] CE-Marked Optical Module.

^{**} Edwards Lifesciences slave cables are bedside monitor specific; they are available for a family of bedside monitor companies such as Philips (Agilent), GE (Marquette) and Spacelabs (OSI Systems). Please contact your Edwards representative for specific model and ordering information.

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Appendix B Equations for Calculated Patient Parameters

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	Table B-1	Cardiac Profile Equations

B-1 Overview

This section describes the equations used to calculate patient parameters displayed on the Cardiac Profile screens.



NOTE

Patient parameters are calculated to more decimal places than are displayed on the screen. For example, a screen CO value of 2.4 may actually be a CO of 2.4492. Consequently, attempts to verify the accuracy of the monitor's display using the following equations may produce results that are slightly different from the data computed by the monitor.



NOTE

Subscript SI = Standard International Units

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Table B-1 Cardiac Profile Equations

Parameter	Description and Formula	
CI	Cardiac Index CI = CO/BSA where: CI - Cardiac Index, CO - Cardiac Output, I/I BSA - Body Surface Area, m ²	(l/min/m ²) min
SVR	Systemic vascular resistance SVR = {(MAP - CVP) x 80} /CO SVR = {(MAP _{SI} - CVP _{SI}) x 60} /CO where: MAP - Mean Arterial Pressure, mmHg MAPSI - Mean Arterial Pressure, kPa CVP - Central Venous Pressure, mmHg CVP _{SI} - Central Venous Pressure, kPa CO - Cardiac Output, I/min	(dyne-sec/cm ⁵) (kPa-sec/l)
SVRI .	Systemic Vascular Resistance Index SVRI = {(MAP - CVP) x 80} /CI SVRI = {(MAP _{SI} - CVP _{SI}) x 60} /CI where: MAP - Mean Arterial Pressure, mmHg MAP _{SI} - Mean Arterial Pressure, kPa CVP - Central Venous Pressure, mmHg CVP _{SI} - Central Venous Pressure, kPa CI - Cardiac Index, I/min/m ²	(dyne-sec-m ² /cm ⁵) (kPa-sec-m ² /l)
SV	Stroke Volume SV = (CO/PR) x 1000 where: CO - Cardiac Output, I/min PR - Pulse rate, beats/min	(ml/beat)
SVI	Stroke Volume Index SV = (CI/PR) x 1000 where: CI Cardiac Index, innimin PR - Pulse rate, beats/min	(ml/beat m ²)
BSA	Body Surface Area (DuBois formula) BSA = 71.84 x (WT ^{0.425}) x (HT ^{0.725}) /10,000 where: WT - Patient Weight, kg HT - Patient Height, cm	(m ²)

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Alexander (Alexander)

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Appendix C Monitor Settings and Defaults

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List of	Table C-1	Upper Alarm Limits	

C-1 Alarm Limits



NOTE

The *Vigileo* monitor will not accept an upper alarm setting that is lower than the lower alarm setting. It also will not accept a lower alarm setting that is higher than the upper alarm setting.

Table C-1 Upper Alarm Limits

Parameter	Upper Limit Range	Setting Increment	Default Value	Units
ScvO ₂ /SvO ₂	11 to 99	1	99	%
CO	2 to 20	1	14	l/min
CI	1 to 20	1	7	I/min/m ²

Table C-2 Lower Alarm Limits

Parameter	Lower Limit Range	Setting Increment	Default Value	Units
ScvO ₂ /SvO ₂	10 to 98	1	10	%
со	1 to 19	1	2	1/min
CI	0 to 19	1	1	l/min/m ²

C-2 Communication Port Default Settings

Table C-3 Communication Port Default Settings

Communication Port	Number of Ports	Default
Analog Input Ports	1	None
Analog Output Port	1	None
Digital Port	COM 1	None

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Appendix D Unit Conversions

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D-1 lbs vs. Kg

Conversion factors:

 $lb \rightarrow Kg$

⇒ Divide lb by 2.2

Kg → lb

⇒ Multiply Kg by 2.2

D-2 inches vs. cm

Conversion factors:

inches → cm

⇒ Multiply inches by 2.54

cm → inches

 \Rightarrow Divide cm by 2.54

D-3 mmHg vs. kPa

 $1 \text{ mmHg} = 1 \text{mmHg}^*$

$$\left(\frac{\text{Newton/m2}}{.0075 \text{ mmHg}}\right) \times \left(\frac{\text{Pa}}{\text{Newton/m2}}\right) \times \left(\frac{1 \text{ kPa}}{1000 \text{ Pa}}\right) = \left(\frac{1 \text{ kPa}}{7.5}\right)$$

or

7.5 mmHg = 1 kPa

Conversion factors:

mmHg → kPa

⇒ Divide mmHg by 7.5

kPa → mmHg

⇒ Multiply kPa by 7.5

D-4 dn-s/cm⁵ vs. kPa-s/l

 $1 \text{ dn-s/cm}^5 =$

$$* \left(\frac{1000 \text{ cm}^3}{1}\right) * \left(\frac{1 \text{ kPa}}{1000 \text{ Pa}}\right)$$

$$= \left(\frac{1 \text{ kPa-s/I}}{10.0}\right)$$

or

 $10.0 \text{ dn-s/cm}^5 = 1 \text{ kPa-s/L}$

Conversion factors:

 $dn-s/cm^5 \rightarrow kPa-s/L$ \Rightarrow Divide $dn-s/cm^5$ by 10.0

 $kPa-s/L \rightarrow dn-s/cm^{5^*} \implies Multiply kPa-s/L by 10.0$

Conversion factors:

 $g/dL \rightarrow mmol/L$

 \Rightarrow Multiply g/dL by 0.6206

 $mmol/L \rightarrow g/dL$

⇒ Divide mmol/L by 0.6206

D-5 g/dl vs. mmo1/l

$$1 \text{ g/dl} = \left(\begin{array}{c} 1 \text{ g} \\ \hline \text{dl} \end{array} \right) * \left(\begin{array}{c} 1 \text{ mol} \\ \hline 64.458 \text{ g} \end{array} \right) * \left(\begin{array}{c} 1000 \text{ mmol} \\ \hline \text{mol} \end{array} \right)$$

$$* \left(\begin{array}{c} 10 \text{ dl} \\ \hline 1 \end{array} \right) * 4$$

$$= \left(\begin{array}{c} 0.6206 \text{ mmol} \\ \hline 1 \end{array} \right)$$

or
$$1 \text{ mmol/l} = \left(\frac{g/dl}{0.6206}\right)$$

Appendix E System Care, Service and Support

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E-1 Overview

The *Vigileo* monitor does not need routine servicing or preventive maintenance to maintain its optimum performance level. It contains no user-serviceable parts, and should be repaired only by qualified service representatives.

This appendix provides instructions for cleaning the monitor and system accessories and contains information on how to contact your local Edwards representative for support and information on repair and/or replacement.



WARNING

The Vigileo monitor contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages.

E-2 Cleaning the Monitor



WARNING

Shock or fire hazard! Do not immerse the *Vigileo* monitor or cables in any liquid solution. Do not allow any fluids to enter the instrument.

Clean the surface of the *Vigileo* monitor with a cloth with a cloth dampened with 70% isopropyl alcohol solution, diluted bleach solution (1 part bleach to 10 parts water), or a non-abrasive liquid commercial cleaner or spray disinfectant.



CAUTION

You can lightly wipe the top, bottom and front surfaces with the cloth, but the monitor screen and its accessories MUST NOT have liquid poured or sprayed directly on them.



CAUTION

DO NOT:

- allow any liquid to come in contact with the power connector, fuse holder, or switches
- allow any liquid to penetrate connectors or openings in the case.
- clean the monitor's rear panel

If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the monitor. Disconnect power immediately and call your local Edwards Representative.



CAUTION

DO NOT attempt to clean the rear panel of the monitor.

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E-3 Cleaning the System Cables

You can decontaminate the system cables using specific disinfectants. Sterile alcohol preps containing 70% alcohol solution can be used to clean the APCO Cable and other accessory cables.



CAUTION

Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing.

- 1. Moisten a clean cloth with disinfectant and wipe the surfaces.
- 2. Follow the disinfectant wipe with rinsing wipes using cotton gauze moistened with sterile water. Use sufficient rinsing wipes to remove all residual disinfectant.
- 3. Dry the surface with a clean dry cloth.



CAUTION

Do not steam, radiate, or EO sterilize.

Do not immerse.

E-4 Cleaning and Sterilizing the Cable and Connector

- 1. Disconnect the cable from the monitor.
- 2. If saline or dextrose solution has entered the transducer connector, soak the connector in distilled water for five minutes in order to dissolve the residue.
- 3. If blood has entered the transducer connector, soak the connector in 3% hydrogen peroxide for five minutes and then rinse in distilled water for 20 minutes.
- 4. Air dry the connector.



CAUTION

If any electrolytic solution is introduced into the transducer connector of the cable while it is connected to the monitor and the monitor is turned on, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts.



CAUTION

Do not immerse the connector in detergent, isopropyl alcohol, or glutaral-dehyde.

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E-4-1 Cleaning and Sterilizing the Cable Jacket

- 1. To clean or disinfect the cable jacket, use suitable agents such as detergent, isopropyl alcohol, or glutaraldehyde to wipe the surface.
- 2. Wipe the cable with distilled water to remove all residue.
- 3. Air dry the connector.



CAUTION

Do not immerse the connector in these cleaning agents.

E-4-2 Drying the Transducer Connector

- 1. Blow dry the transducer connector with clean, dry wall air, canned air, or CO₂ aerosol for at least two minutes.
- 2. If left to dry under room conditions, allow the connector for two days before using the APCO cable.



CAUTION

Do not use a hot air gun to dry the connector.

E-5 Cleaning the Optical Module

The fiberoptic interface of the optical module must be kept clean. The optical fibers within the oximetry catheter fiber optic connector mate with the optical fibers in the optical module. Use sterile alcohol preps containing 70% isopropyl alcohol solution to clean the optical module housing and the connecting cable, as sterile alcohol preps do not leave a residual film after use.

Moisten a cotton-tipped applicator with sterile alcohol and apply gentle pressure to clean the optical fibers recessed within the front of the optical module.



CAUTION

Do not steam, radiate, or EO sterilize.

Do not immerse.

E-6 Service and Support

See Chapter 12: Troubleshooting on page 12-1 for diagnosis and remedies. If this information does not solve the problem, contact Edwards Lifesciences.

Edwards provides monitor operations support:

- Within the United States and Canada, call 1.800.822.9837.
- Outside the United States and Canada, contact your local Edwards Lifesciences representative.
- E-mail operational support questions to tech_support@edwards.com.

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Have the following information before you call:

- The monitor's serial number, located on the rear panel;
- Software version which is displayed at the bottom of the screen during monitor initialization;

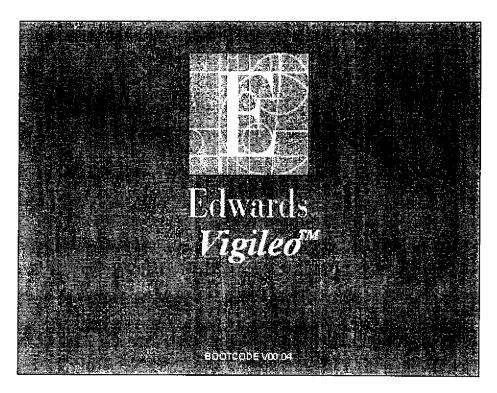


Figure E-1 Vigileo Bootcode screen

 The text of any error message and detailed information as to the nature of the problem.

E-7 Edwards Lifesciences Locations

Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA 949.250.2500 800.424.3278 www.edwards.com

Edwards Lifesciences (Canada) 1290 Central Parkway West, Suite 300 Mississauga, Ontario Canada L5C 4R3 905.566.4220 800.268.3993

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Edwards Lifesciences S.A. Ch. du Glapin 6 1162 St-Prex Switzerland 41.21.823.4300

Edwards Lifesciences Japan 2-8 Rokubancho Chiyoda-ku, Tokyo 102-0085 Japan 81.3.5213.5700

E-8 Monitor Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure the monitor and/or cables are disinfected and decontaminated appropriately in accordance with your country's laws for equipment containing electrical and electronic parts prior to disposal.

For single use parts and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

E-9 Preventative Maintenance

Periodically, examine the monitor exterior for general physical condition. Make sure the housing is not cracked, broken or dented, that everything is present. Make sure there is no sign of spilled liquids or signs of abuse.

Routinely inspect cords and cables for fraying and cracks, and make sure there are no exposed conductors.

E-10 Warranty

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Edwards Lifesciences (Edwards) warrants that the Vigileo monitor is fit for the purposes and indications described in the labeling for a period of one (1) year the date of purchase when used in accordance with the directions for use. Unless equipment is used in accordance with such instructions, this warranty is void no effect. No other express or implied warranty exists, including any warranty merchantability or fitness for a particular purpose. This warranty does not include cables, probes, or optical modules used with this Vigileo monitor. Edwards' sole obligation and purchaser's exclusive remedy for breach of any warranty limited to repair or replacement of the Vigileo monitor is at Edwards' option.

Edwards shall not be liable for proximate, incidental, or consequential damages. Edwards shall not be obligated under this warranty to repair or replace a damaged malfunctioning Vigileo monitor if such damage or malfunction is caused customer's use of catheters other that those manufactured by Edwards.

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Appendix F Guidance and Manufacturer's Declaration

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F-1 Electromagnetic Compatibility

Reference: EN 60601-1-2:2001

The *Vigileo* monitor is suitable for use in the specified electromagnetic environment. The customer and/or user of the *Vigileo* monitor should ensure that it is used in an electromagnetic environment as described below.

F-2 Instructions for Use

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following information and tables.



WARNING

Use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the *Vigileo* monitor.



WARNING

The *Vigileo* monitor should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, the *Vigileo* monitor should be observed to verify normal operation in the configuration in which it is used.



WARNING

There are minimum amplitudes for the *Vigileo* monitor to measure physiological signals. Operation of the equipment below the minimum amplitudes may cause inaccurate results.

Table F-1 Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions	Compliance	
RF emissions CISPR 11	Group 1	The Vigileo monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The Vigileo monitor is suitable for use in domestic establishments and in
Harmonic emissions IEC 61000-3-2	Class A	establishments directly connected to a low voltage power supply network that supplies
Voltage fluctuation/ Flicker emissions IEC 61000-3-3	Complies	buildings used for domestic purposes.

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Table F-2 Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment -Guidance
Electrostatic discharge	±2, ±4, ±6 kV contact	±2, 4, 6 kV	Floors should be wood,
(ESD) IEC 61000-4-2	±2, ±4, ±8 kV air	±2, 4, 8 kV	concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/	±1 kV AC Mains	Not ApplicableAll	Mains power quality should be
burst IEC 61000-4-4	Differential mode	I/O < 3 meters	that of a typical commercial and/or hospital environment.
	±2 kV AC Mains		
	Common mode		
	±1 kV I/O Lines		
	I/O > 3 meters		
AC Power Mains	+/- 0.5, +/- 1 kV differential mode	+/-0.5, 1 kV	
	+/- 2 kV common mode	+/-2 kV	
Measurement I/O	N/A, < 3 meters	N/A	
Surge	±0.5, ±1 kV differential mode	±1 kV	
IEC 61000-4-5	±0.5, ±1, ±2 kV common mode	±2 kV	
Voltage dips, short interruptions and voltage variations on power supply AC input lines	. <5% $U_{\rm T}$ (>95% dip in $U_{\rm T}$) for 0.5 cycle	<5% <i>U</i> _T	Mains power quality should be that of a typical commercial and/or hospital environment. If the <i>Vigileo</i> monitor user
	$40\%U_{\mathrm{T}}$ (60% dip in U_{T}) for 5 cycles	40% U _T	
IEC 61000-4-11	70% U _T (30% dip in U _T) for 25	70% U _T	requires continued operation during power mains
1000-4-11	cycles	'	interruptions, we
	<5% U _T (>95% dip in U _T)for 5	<5% U _T	recommended the Vigileo monitor be powered by an uninterruptible power supply or battery.
	sec		
Power frequency	3 A/m	3 A/m	Power frequency magnetic
(50/60 Hz) magnetic			fields should be at levels
field			characteristic of a typical
IEC 61000-4-8			location in a typical commercial or hospital environment.

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Table F-3 Electromagnetic Immunity (RF Radiated and Conducted)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
·			Portable and mobile RF communication equipment should be used no closer to any part of the <i>Vigileo</i> monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6			Recommended Separation Distance
Radiated RFIEC 61000-4-3	3 Vms150 kHz to 80 MHz	1 Vrms	d = [3.5] x √ P; 150 kHz to 80 MHz
			$d = [1.2] \times \sqrt{P}$; 80 kHz to 800 MHz
	3 V/m80 to 2500 MHz	3 V/m	$d = [2.3] \times \sqrt{P}$; 800 kHz to 250
•			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment with the following symbol:

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Vigileo* monitor is used exceeds the applicable RF compliance level above, the *Vigileo* monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Vigileo* monitor.

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 $^{^{\}rm b}$ Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table F-4 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the *Vigileo* monitor

The *Vigileo* monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. To help prevent electromagnetic interference, maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Vigileo* monitor as recommended below, according to the maximum output power of the communications equipment.

Transmitter Frequency	150 kHz to 80 MHz	80 to 800 MHz	800 to 2500 MHz
Equation	d = [1.2] x 5 \P	d= [1.2] x 2 \P	d= [2.3] x \P
Rated Maximum Output Transmitter Power(watts)	Separation Distance (meters)	Separation Distance (meters)	Separation Distance (meters)
0.01	0.4	0.1	0.2
0.1	1.1	0.4	0.7
1	3.5	1.2	2.3
10	11	3.8	7.3
100	35	12	23

For transmitters rated at a maximum output power not listed above, the separation distance d can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table F-5 List of Accessories, Cables and Transducers Necessary for Compliance

Description	Length
APCO cable	9'
APCO Disposable Pressure Transducer	15"
OM2 Optical Module	8.7'

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Appendix G Glossary

Alarms

Audible and visual indicators that notify operator that a measured patient parameter is outside the alarm limits.

Alarm Limits

Maximum and minimum values for monitored patient parameters.

APCO

(Arterial pressure cardiac output) CO continuously estimated from the blood pressure waveform.

Body Surface Area (BSA)

Surface area of a patient's skin.

Cardiac Index (CI)

Cardiac output adjusted for body size.

Cardiac Output (CO)

Volume of blood ejected per minute from the heart into the systemic circulation.

Central Venous Pressure (CVP)

Mean pressure in the superior vena cava. Indicates venous return to the right side of the heart.

Central Venous Oxygen Saturation

Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the pulmonary artery. Displayed as ScvO₂.

Default Settings

Initial operating conditions assumed by the monitor.

Hematocrit (Hct)

Percentage of blood volume that contain red blood cells.

Hemoglobin (HGB)

Oxygen carrying component of red blood cells. Volume of red blood cells measured in grams per deciliter.

lcon

An image that represents a specific screen, window, file, or program.

Mean Arterial Pressure (MAP)

Average systemic arterial blood pressure.

Mixed Venous Oxygen Saturation

Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the pulmonary untry. Displayed as SvO₂.

Oximetry (Oxygen Saturation, ScvO₂/ SvO₂)

Percentage of hemoglobin saturated with oxygen in the blood.

Pulse Rate (PR)

Number of ventricular contractions per minute as counted by the systolic pressure measurements from the arterial catheter.



Slave Cable

Cable that transfers data to the *Vigileo* monitor from another monitor.

Stroke Volume (SV)

Amount of blood ejected from the ventricles with each contraction.

Stroke Volume Variation (SVV)

Stroke volume variation is the percent difference between systolic measurements.

Stroke Volume Index (SVI)

Stroke volume adjusted for body size.

Systemic Vascular Resistance (SVR)

A derived measure of impedance to blood flow from left ventricle (afterload).

Systemic Vascular Resistance Index (SVRI)

Systemic vascular resistance adjusted for body size.

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B 1

DDPT Shipping Container Labeling

Edwards Lifesciences

REF: MHD002NCT

Qtv. 10

PRESSURE MONITORING KIT — STERILE

Edwards Lifesciences LLC Irvine, CA 92614 – 5686 USA Made in USA

Lot No. DODAXDOOYY

(01) 5 06 90103 16608 3

Use By: 2006 — 10

(10) 000AX000YY(17) 061000

C7215G6B

A 10011436

ifesciences Wards

For single use only See package insert for detailed information. Do not use if package is opened or damaged. Store in a cool, dry place. Rx only

Edwards Lifesciences LLC Irvine, CA 92614-5686 USA

BAR CODE FPO

Made in USA

9

192714BB1A

254

DDPT Unit Labeling



Edwards Lifesciences

For single use only Ethylene oxide sterilized

Rx only Store in a cool, dry place. Contents of package sterile and nonpyrogenic if unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize. See package insert for detailed information.

Edwards Lifesciences LLC Ivvine, CA 92614-5686 USA Made in USA 171609004 A

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Qty. 1

PRESSURE MONITORING KIT - STERILE

Lot No. OOOAXOOOYY

Use By: 2006 - 10

6 90103 16608 8

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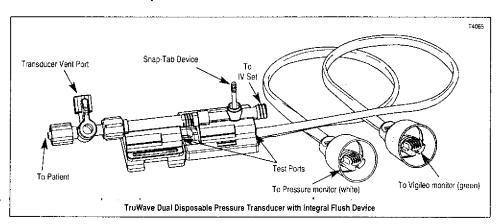
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DDPT Directions for Use

E Edwards Lifesciences

Pressure Monitoring Kit with TruWave Dual Disposable Pressure Transducer



For single use only

These are general instructions for setting up a pressure monitoring system with the TruWave dual disposable pressure transducer. Since kit configurations and procedures vary according to hospital preferences, it is the responsibility of the hospital to determine exact policies and procedures.

Caution: The use of lipids with the TruWave dual disposable pressure transducer may compromise product integrity.

Concept/Description

The Edwards pressure monitoring kit with the TruWave dual disposable pressure transducer is a sterile, single use kit that monitors pressures when attached to pressure monitoring catheters. The disposable sterile cable with a white connector interfaces exclusively with an Edwards cable with a white connector interfaces exclusively with an Edwards cable that is specifically when on the pressure monitor being used. The disposable sterile cable with a green connector interfaces exclusively with the Edwards APCO cables for use with the Edwards pulse pressure based cardiac output monitoring devices or hardware.

The TruWave dual disposable pressure transducer has a straight, flow-through design across the pressure sensors with an integral flush device.

Edwards Lifesciences, the stylized E logo, Edwards, TruCal, TruWave and Vigileo are trademarks of Edwards Lifesciences Corporation, TruWave is registered in the U.S. Patent and Trademark Office.

Indications

The pressure monitoring kit with TruWave dual disposable pressure transducer is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards pulse pressure based cardiac output monitoring devices or hardware to measure cardiac output.

Contraindications

There are no absolute contraindications for using the TruWave dual disposable pressure transducer in patients requiring invasive pressure monitoring.

Procedure

- Ensure that the cables are compatible with the monitors being used.
 Connect the reusable cables to the monitors, and turn the monitors on to allow the electronics to warm up.
- Using aseptic technique, remove the transducer and kit from the sterile packaging.
- Add additional components as needed to complete the monitoring system per hospital policy.
- 4. Ensure that all connections are secure.
- Connect the transducer cable with the white shield to the reusable cable appropriate for the pressure monitor.
- Connect the transducer cable with the green shield to the Edwards' APCO cable.

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- Remove all air from the heparinized IV flush solution bag per hospital policy.
 - Caution: If all air is not removed from the bag, air may be forced into the patient's vascular system when the solution is exhausted.
- Close the roller clamp on the IV set and connect the IV set to the IV flush bag. Hang the bag approximately 2 feet (60 cm) above the pattent. This height will provide approximately 45 mmHg of pressure to prime the setup.
- Fill the drip chamber halfway with flush solution by squeezing the drip chamber. Open the roller clamp.
- Flow is provided by pulling on the Snap-Tab device and discontinued by releasing the Snap-Tab device.
- 11. For kits with IV sets attached, open the transducer vent port by turning the stopcock handle. Deliver flush solution first through the transducer and out through the vent port, then through the remaining kit by turning the appropriate stopcocks. Remove all air bubbles.
 - Caution: Significant distortion of the pressure waveform or air emboli can result from air bubbles in the setup.
- Replace all vented caps on sideports of the stopcocks with nonvented caps.
- Mount the transducers on an IV pote using the appropriate clamp and holder. Snap transducer into place in holder.
- 14. Pressurize the IV flush solution bag. Flow rate will vary with pressure across the flush device. The flow rates with the IV bag pressurized to 300 mmHg are as follows.
 - 3 ± 1 ml/hr (DPT with blue Snap-Tab device)
- Connect pressure tubing to the catheter per manufacturer's instructions.
- 16. Flush system per hospital policy.

Caution: After each fast-flush operation, observe the drip chamber to verify that the continuous flush rate is as desired (see Complications).

Zeroing and Calibration

- Adjust the level of the top transducer vent port (the fluid-air interface) to correspond to the chamber where pressure is being measured.
 For example, in cardiac monitoring, zero at level of the right atrium.
 This is at the phiebostatic axis, determined by the intersection of the midaxillary line and the fourth intercostal space.
- 2. Remove the non-vented cap and open the vent port to the atmosphere.
- Adjust the pressure monitor to read zero mmHg
- Check pressure monitor calibration using procedure recommended by the monitor manufacturer.
- 5 Use the model TruCal pressure transducer simulator/tester in conjunction with the Model PXSIM (TruWave pressure transducer simulator/tester tubing set) to verify pressure readings without compromising sterility of the system (Figure 1).
 - Instructions are included with the TruWave pressure transducer simulator/tester tubing set.

- Close the vent port to the atmosphere and replace the nonvented cap.
- 7. System is ready to begin monitoring pressure.

Testing Dynamic Response

The assembly may be tested for dynamic response by observing the pressure waveform on an oscilloscope or monitor. Bedside determination of the dynamic response of the catheter, monitor, kit, and transducer system is done after the system is flushed, attached to the patient, zeroed, and calibrated. A square-wave test may be performed by pulling the Snap-Tab device and releasing quickly.

Note: Poor dynamic response can be caused by air bubbles, clotting, excessive lengths of tubing, excessively compliant pressure tubing, small bore tubing, loose connections, or leaks.

Routine Maintenance

Follow hospital policies and procedures for frequency of zeroing the transducer and pressure monitor and for replacing and maintaining pressure monitoring lines. The TruWave dual disposable pressure transducer is precalibrated and has a negligible drift with time (see Specifications).

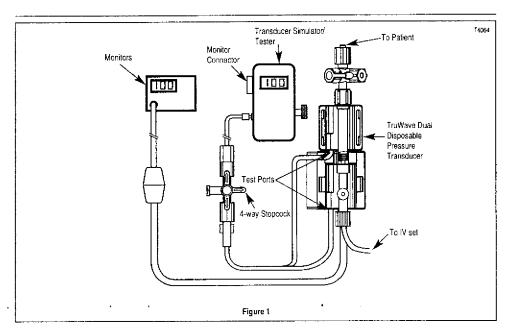
- Adjust zero pressure reference each time level of the patient is changed.
 - Caution: When rechecking zero or verifying accuracy, ensure that the non-vented cap is removed before opening the transducer vent port to the atmosphere.
- Periodically check fluid path for air bubbles. Ensure that connecting lines and stopcocks remain tightly fitted.
- Periodically observe the drip chamber to verify that the continuous flush rate is as desired.
- The Centers for Disease Control recommends replacing disposable or reusable transducers at 96-hour intervals. Replace other components of the system, including the tubing, continuous-flush device, and flush solution, at the time the transducer is replaced.

Warnings

- Do not use the flush device during intracranial pressure monitoring.
- High pressures, which may be generated by an infusion pump at certain flow rates, may override the flush device restriction, resulting in fast flushing at the rate set by the pump.
- Do not allow air bubbles to enter the setup, especially when monitoring atrial pressures.
- Avoid contact with any topical cream or ointment that attacks polymeric materials.
- · Do not expose electrical connections to fluid contact.
- Do not autoclave the reusable cable.



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Complications

Sepsis/Infection

Positive cultures can result from contamination of the pressure setup. Increased risks of septicemia and bacteremia have been associated with blood sampling, infusing fluids, and catheter related thrombosis (Refs. 1, 2 & 7).

Air Emboli

Air can enter the patient through stopcocks that are inadvertently left open, from accidental disconnection of the pressure setup, or from flushing residual air bubbles into the patient (Ref. 6).

Clotted Catheter and Bleed-Back

If the flush system is not adequately pressurized relative to the patient's blood pressure, blood bleed-back and patients station manufacture.

Overinfusion

Excessive flow rates may result from pressures greater than 300 mmHg. This may result in a potentially harmful increase in blood pressure and fluid overdose (Ref. 3).

Abnormal Pressure Readings

Pressure readings can change quickly and dramatically because of loss of proper calibration, loose connection, or air in the system (Refs. 3 & 6).

Warning: Abnormal pressure readings should correlate with the patient's clinical manifestations, Verify transducer function with a known amount of pressure before instituting therapy.

How Supplied

TruWave dual disposable pressure transducers are supplied sterile in preconnected monitoring kits (either standard design or special order). Contents sterile and fluid path nonpyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Do not resterlize.

Technical Assistance

lamida the LLC and Conside

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

(24 hours)	800.822.9837
Outside the U.S. and Canada (24 hours)	949.250.2222
Carthor: Federal (GSA) law in stricts this device to sall order of a physician.	le by or on the

Prices, specifications, and model availability are subject to change without notice

This product is manufactured and sold under one or more of the following US patent(s): US Patent No. 4,576,181; 4,610,256; 5,564,951; 5,803,770; and corresponding foreign patents. Likewise, additional patents pending.

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В

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TruWave Dual Disposable Pressure Transducer	
Operating Pressure Range	-50 to +300 mmHg
Operating Temperature Range	15° to 40°C
Storage Temperature Range	-25° to +70°C
Sensitivity	5.0μ V/V/mmHg ± 1%
Nonlinearity and Hysteresis	± 1.5% of reading or ± 1 mmHg, whichever is greater
Excitation Impedance	350 ohms ± 10% with typical Edwards Monitor Cable attached
Signal Impedance	300 ± 5%
Zero Offset	≤ ± 25 mmHg
Zero Thermal Drift	≤ ± 0.3 mmHg/°C
Output Drift	± 1 mmHg per 8 hours after 20 second warm-up
Sensitivity Thermal Drift	≤ ± 0.1%/°C
Natural Frequency	40 Hz nominal for a standard kit (48"/12"); >200 Hz for transducer alone
Defibrillator Chailenge	withstands 5 repeated discharges of 360 Joules within 5 minutes delivered into a 50 ohm load
Leakage Current	<2µ amps at 120V RMS 60 Hz
Overpressure Tolerance	-500 to +5000 mmHg
Shock Resistance	withstands 3 drops from 1 meter
Light Sensitivity	< 1 mmHg at 6 volts excitation when exposed to a 3400°K tungsten light source at 3000 foot candles
Volumetric Displacement	≤ 0.03 mm³/100 mmHg per transducer
Flow rate across flush device with IV bag pressurized to 300 mmHg Blue Snap-Tab device	3 ± 1 mVhr

All specifications meet or exceed the AAMI Standard for performance interchangeability of resistance bridge type blood pressure transducers.

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Manufactured by an affiliate of: Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686 USA

Telephone 949.250.2500 800.424.3278 FAX 949.250.2525

Made in USA

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Appendix C

Predicate Labeling

CONFIDENTIAL

Vigilance Monitor Shipping Label



Edwards Lifesciences

REF: VGS2V

Qty. # :1

Vigilance Monitor ■ Moniteur Vigilance Vigilance-Monitor ■ Monitor Vigilance ■ Monitor Vigilance

This product is manufactured and sold under one or more of the following US patent(s): US Patent No. 4,507,974; 4,651,741; 5,146,414; 5,305,760; 5,553,622; 5,588,438; 5,634,470; 5,687,733; 5,701,908; 5,720,293; 5,755,670; 6,045,512; and corresponding foreign patents. Likewise, additional patents pending.

Ce produit est fabriqué et vendu sous un ou plusieurs des brevets ci-après : brevet US N° 4 507 974 ; 4 651 741 ; 5 146 414 ; 5 305 760 ; 5 553 622 ; 5 588 438 ; 5 634 470 ; 5 687 733 ; 5 701 908 ; 5 720 293 ; 5 755 670 ; 6 045 512 ; ainsi que des brevets étrangers correspondants. De même, d'autres brevets sont en cours.

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5.146.414; 5.305.760; 5.553.622; 5.588.438; 5.534.470; 5.687.733; 5.701.508; 5.720. ed i corrispondenti brevetti stranieri. Inoltre, ulteriori brevetti sono in corso.

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Vigilance Monitor Unit Label



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100-240 V ~

50-60 Hz

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4,651,741; 5,146,414; 5,305,760; 5,553,522; 5,588,438; 5,687,733; 5,634,470; 5,701,908; 5,720,293; 5,755,670; 6,045,51 and corresponding foreign patents. RX only Ce produit est tabiqué et vendu sous un ou plusieurs des brevets cr-après : brevet US N° 4,507,974; 4,661,741; 5,146,414; 5,305,760; 5,553,622; 5,558,438; 5,667,733; 5,634,470; 5,701,908; 5,720,293; 5,755,670; 6,045,512; ainsi que des brevets étrangers correspondants.

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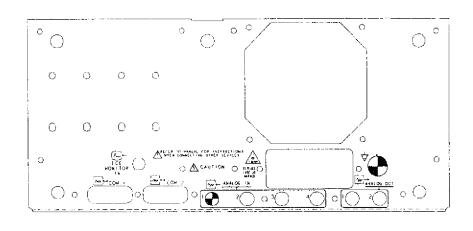
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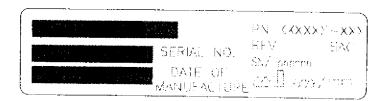
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Vigilance Monitor Rear Panel Labels







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Vigilance Monitor Operator's Manual

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Operator's Manual

Vigilance

Continuous Cardiac Output (CCO) Monitors,

Continuous Cardiac Output/Volumetric (CCO/CEDV) Monitors, Continuous Cardiac Output/Oximetry (CCO/SvO $_2$) Monitors and

Continuous Cardiac Output/Oximetry/Volumetric (CCO/SvO₂/CEDV) Monitors



C **011**

Edwards Lifesciences *Vigilance* Monitor Operator's Manual February 2004

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Caution:

Federal (USA) law restricts this device to sale by or on the order of a physician.

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Preface

❖ WARNING: CAREFULLY READ THIS OPERATOR'S MANUAL BEFORE ATTEMPTING TO USE THE *Vigilance* MONITOR.

Purpose and Scope

The purpose of this manual is to provide the operator of the *Vigilance* Monitor with setup and operating instructions, device applications, limitations, and routine performance verification procedures. The *Vigilance* Monitor Operator's Manual provides instructions for all *Vigilance* Monitor configurations*. To achieve satisfactory results, the operator should read this manual thoroughly before attempting to use the monitor.

Audience

This manual has been prepared for use by trained critical care clinicians, nurses, and physicians in any hospital environment where critical care is administered (for example, emergency rooms, operating rooms, intensive care units, etc.).

*Vigilance Monitors may be configured to perform CCO/ICO measurements only or CCO/ICO and Oximetry measurements. The monitors may also be configured to perform CEDV measurements. For Vigilance monitors without Oximetry capabilities, disregard all references to Oximetry capabilities in this manual. For Vigilance monitors without CEDV capabilities, disregard all references to CEDV capabilities in this manual.

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Notation Conventions	BOLDFACE SMALL CAPS	Within paragraph text, defines the name of a key or screen. Example: To mark an event press the HOME key.
	ALL CAPS	Within paragraph text, used to emphasize an action or mode of operation. Example: The instrument default setting is the AUTOMATIC mode.
	▲ CAUTION	Denotes items that require special attention by the operator. Cautionary items are shown in boldface type.
	❖ WARNING	Denotes items that require extreme caution by the operator to prevent possible injury to the operator or the patient. WARNINGS ARE SHOWN IN ALL CAPS.
	→ NOTE	Denotes items that are considered to be important in explaining an operation or procedure and are separate from normal text to draw attention to them.

CHAPTER

1 INTRODUCTION

1. Introducing the Vigilance Monitor

The Vigilance Monitor is an advanced patient monitor which measures cardiac output both continuously and by the intermittent bolus thermodilution method. The Vigilance Monitor may also be configured to measure continuous Oximetry (oxygen saturation, SvO₂) as well as continuous end diastolic volume (EDV). In addition, the Vigilance Monitor calculates hemodynamic and oxygenation parameters. The Vigilance Monitor is designed for use by trained clinicians in a variety of critical care settings including operating rooms, intensive care units, cath labs, and recovery rooms, as well as hospital emergency rooms, cardiac care, and burn units.

The *Vigilance* Monitor measures cardiac output continuously by introducing small pulses of energy into the blood and recording blood temperature via a pulmonary artery catheter. Cardiac output is computed using a conservation of heat equation, and indicator dilution curves are obtained by cross-correlation of the energy input and blood temperature waveforms. After initialization, the monitor continuously displays the patient's cardiac output without the need for user calibration or intervention.

To measure cardiac output intermittently using the bolus thermodilution technique, a small amount of indicator of a known volume and temperature is injected through the catheter injectate port, and the resultant decrease in blood temperature is measured by the thermistor in the Pulmonary Artery (PA). The *Vigilance* Monitor plots a curve representing the decrease in blood temperature over time and integrates the data based on the Stewart-Hamilton indicator dilution equation. The area beneath the thermodilution curve is calculated and displayed in numeric form (in liters per minute).

To measure continuous end diastolic volume the *Vigilance* monitor uses the same continuous cardiac output (CCO) technology to obtain the indicator dilution curves. Ejection fraction is computed based on the curve's exponential slope and the continuous average heart rate obtained from the slaved-in patient's ECG signal. Continuous end diastolic volume is then calculated from the ejection fraction, heart rate and cardiac output measurements without the need for user calibration or intervention.

Vigilance Monitors measure Oximetry (oxygen saturation) by a spectrophotometric technique that uses light emitting diodes (LEDs) to transmit light in the red and infrared spectra through an optical fiber in a PA catheter to the blood. The light is reflected back through a separate optical fiber to an optical module. The amount of light reflected is primarily dependent on the color and amount of red blood cells present. The reflected light is electrically measured by the Vigilance Monitor and analyzed to determine Oximetry by detecting color changes in the red blood cells.

The Vigilance Monitor derives parameter values related to hemodynamics and oxygenation with appropriate user input.

1-2

2

QUICK-START GUIDE TO OPERATION

2. Quick-Start Guide to Operation

This *Quick-Start Guide to Operation* is intended only as a checklist for operating the *Vigilance* Monitor. The user should thoroughly read this manual before attempting to use this instrument.

Vigilance Monitor is for use only as an adjunct in patient assessment. This instrument should be used in conjunction with other clinical indicators.

Before using the *Vigilance* Monitor, the user should thoroughly read the directions for catheter use provided with each catheter for complete description, instructions, warnings, cautions, and specifications.

- ❖ WARNING: IMPROPER USE OF THE Vigilance MONITOR COULD PRESENT A HAZARD TO THE PATIENT. CAREFULLY READ THE "WARNINGS" SECTION OF THIS MANUAL (Section 3.9) BEFORE USING THE INSTRUMENT.
 - 1. Attach one end of the power cord securely to the *Vigilance* Monitor and connect the other end to an AC power outlet.
 - 2. Turn the *Vigilance* Monitor on by pressing the green power switch located at the lower left on the front of the monitor. The small green LED will light ap and the video screen will display a self-test message. The monitor will then proceed with initialization.
 - 3. Carefully align the instrument end of the catheter interface cable with the corresponding receptacle located at the bottom right of the monitor. Push the connector straight in until fully seated.
 - **4.** In order to acquire Oximetry measurements, connect the optical module to the SvO₂ connector on the front of the *Vigilance* Monitor. **Allow 20 minutes for optical module warm up.**
 - 5. If continuous EDV monitoring is required, connect the ECG slave cable's 1/4 inch miniature phone plug to the ECG monitor input on the rear panel of the *Vigilance* unit, and connect the other end of the slave cable to the patient's bedside monitor's ECG signal output.

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- **6.** Following the internal self-test and initialization, the **HOME** screen is displayed.
- 7. If Oximetry monitoring is desired:
 - i. Connect the catheter to the optical module.
 - ii. Press **SvO**₂ on the touch bar.
 - iii. Select IN VITRO CALIBRATION on the touch bar.
 - iv. Use the **CURSOR** key to select Hgb (hemoglobin) or Hct (hematocrit). Enter lab value using touch bar. If the lab value is not available or unknown, the default values can be used until the lab value is available. (When the lab value is available, see the HGB Update instructions in section 3.5.6).
 - v. Press the CAL key. The following message will be displayed:

In Vitro Calibration in progress.

Upon completion of a successful calibration, the monitor will display the following message:

In Vitro Calibration OK. Insert catheter then press Start SvO2.

- **8.** Prepare the catheter for insertion (see package insert that accompanies the catheter).
- 9. If Oximetry monitoring is desired and the catheter is properly positioned in the patient, press START SvO₂ on the touch bar. The following message will be displayed:

Optical Module Update in progress.

The **HOME** screen will automatically be displayed with an SvO₂ value.

- 10. If CCO monitoring is desired, press the CCO key to begin the continuous cardiac output monitoring process. Continuous EDV monitoring will also begin if the patient's ECG signal is slaved into the monitor.
- 11. The five function keys (CCO (STOPPED/RUNNING), TREND, PATIENT DATA, SETUP, and ALARMS), located vertically to the right of the screen, provide access to optional screens which will, in turn, change the functions and labels of individual keys. The blue touch bar located below the display screen allows for operating mode changes and data entry based upon the function selected.

1

3

OPERATING THE VIGILANCE MONITOR

3. Overview

The Vigilance Monitoring System consists of the following components: monitor, detachable catheter patient interface cable, optical module*, ECG slave cable**, flow-through temperature probe, and power cord. The monitor is principally intended for use with Edwards catheters designed to continuously measure cardiac output and/or Oximetry (oxygen saturation.) Alternatively, the monitor can be used to measure cardiac output intermittently, through the BOLUS CO mode, using compatible thermodilution pulmonary artery catheters.

NOTE: User entered values are shifted into the selected field from the right-most digits. The first digit entered will cause the decimal point and any necessary 0's (place holders between the right-most position and the decimal point) to appear. Additional digits shift in from the right.

*Optical modules are only provided with those *Vigilance* Monitors that are going to be used for Oximetry measurement.

**ECG slave cables are only provided with those *Vigilance* Monitors that are configured for continuous EDV measurement.

3.1 **Controls** and Basic Operation

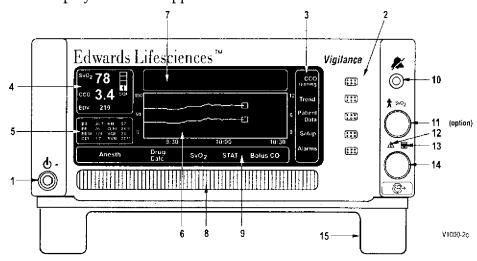
3.1.1 CONTROLS

Figure 3-1 Vigilance Monitor, Front Panel

For Vigilance monitors not configured with Oximetry, SvO₂ display items will not appear.

For Vigilance monitors not configured for Continuous EDV, the EDV

display items will appear with no associated values.



1. POWER SWITCH

Green button turns the instrument power ON and OFF.

2. FUNCTION KEYS

Five keys provide direction to general operating functions:

- CCO (STOPPED/RUNNING)-key: Starts or stops the chosen mode of cardiac output measurement — either continuous or bolus.
- **TREND** key: Allows the user to vary the time scale duration (30 minutes to 24 hours). Also allows the user to select patient parameters to graph, to change the vertical scale, and to mark events.
- PATIENT DATA key: Provides for review of calculated hemodynamic and oxygenation parameters and manual entry of patient data.
- **SETUP** key: Provides for selection of display units, audio level, setting internal clock, and auxiliary functions.
- **ALARMS** key: Allows the user to control the alarm monitoring function by selecting patient parameters to be monitored and by establishing alarm limits.

3. FUNCTION KEY LABELS

- 4. LARGE NUMERIC DISPLAY AREA
- 5. SMALL NUMERIC DISPLAY AREA

- GRAPH OR MENU AREA
- 7. MESSAGE WINDOW FOR FAULTS. ALARMS, ALERTS

8. TOUCH BAR

The blue bar is used to select options for touch pad functions and allows for operating mode changes and numeric data entry.

9. TOUCH BAR LABELS

10. ALARM SILENCE KEY

The orange button silences the audible alarm for two minutes or until all alarm conditions are cleared, whichever occurs first.

11. OFFICAL MODULE CONNECTOR

This provides the interface for the OM2 cable. (On monitors equipped with Oximetry capabilities)

12. CAUTION

Before connecting cable, refer to Operator's Manual.

13. CAUTION

Connections are electrically isolated from earth ground.

14. CATHETER CABLE CONNECTOR

This connector provides the interface for the patient cable.

15. TILT STAND

Pulls down to raise monitor screen for viewing.

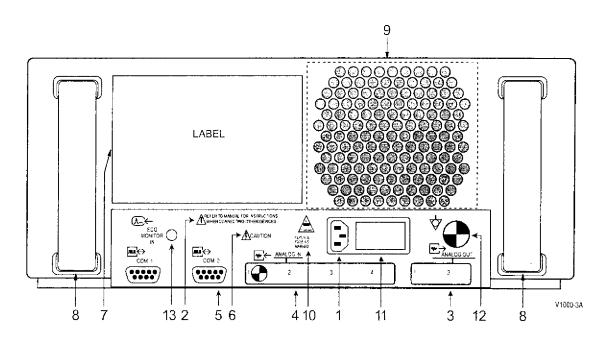


Figure 3-2. Vigilance Monitor, Rear Panel

1. AC POWER INPUT

Use only the power cord supplied with the monitor. This connector accepts AC power ranging from 100 to 240 VAC, 50/60 Hz.

2. CAUTION

For safe operation, see Section 3.7 for instructions before connecting other devices.

3. ANALOG OUT

These 2 connectors provide the user with selectable analog signals for output to a chart recorder or other instruments via a 1/8 inch miniature phone plug.

4. ANALOG IN

These 4 connectors provide the instrument with input signals from other equipment via 1/8 inch miniature phone plugs.

5. COM1/COM2

These 2 connectors allow for connecting the instrument to a printer, or other clinical instrument, or other manufacturer's instruments, via 9-pin RS-232 connectors.

6. CAUTION

To reduce the risk of electric shock, DO NOT remove back. Refer servicing to qualified service personnel.

7. INSTRUMENT SERIAL NUMBER

Numerical identification required when contacting Edwards Technical Support.

8. HANDLES

The plastic handles provide convenient portability for the instrument.

9. FAN OUTPUT

Opening allows for air output from the instrument fan.

10. CAUTION

Replace fuse as marked.

11. FUSE HOLDER

12. EQUIPOTENTIALITY GROUND

13. ECG MONITOR IN

This connector provides the instrument with the ECG input signal from a bedside monitor via 1/4 inch miniature phone plug.

3.1.2 PREPARING INSTRUMENT FOR BASIC OPERATION

The following procedure describes the steps to be performed in setting up the *Vigilance* Monitor for basic operation:

- Attach one end of the power cord securely to the Vigilance Monitor and connect the other end to an AC power outlet.
- 2. Turn the *Vigilance* Monitor on by pressing the green power switch located at the lower left on the front of the monitor. The small green LED will light up and the video screen will display a self-test message. The monitor will then proceed with initialization.
- ▲ CAUTION: Ensure that the ventilation fan is operating properly through the fan output on the instrument rear panel.
 - Monitor will prompt the user to confirm that a new patient is being connected. If new patient is confirmed, all previously recorded patient and trend data will be deleted. Otherwise, the data will be saved. If the monitor power is off for more than eight hours, patient data is automatically deleted and no new patient confirmation is required.
 - **3.** To prepare the *Vigilance* Monitor for CCO monitoring, carefully align the instrument end of the catheter interface cable with the corresponding receptacle located at the bottom right of the monitor. Push the connector straight in until fully seated.
 - If Oximetry monitoring is desired, connect the optical module to the SvO₂ connector on the front of the instrument to prepare for monitoring.
 - NOTE: If the optical module is being connected for the first time or the system has been turned off with the optical module connected, allow 20 minutes for optical module warm up. The catheter need not be connected to the optical module for it to warm up.
 - 5. If continuous EDV monitoring is desired, connect the ECG slave cable's 1/4 inch miniature phone plug to the ECG monitor input on the rear panel of the *Vigilance* unit, and connect the other end of the slave cable to the patient's bedside monitor's ECG signal output.
 - **6.** Following the internal self-test and initialization, the **HOME** screen is displayed. The instrument will emit a beep and display a message to check the catheter connection, for example:

FAULT: Check Catheter and Cable Connections

The following message will be displayed during SvO₂ initialization:

SvO2 Initializing, Please Wait

The following message will be displayed when the SvO₂ initialization is complete:

Optics Module Not Calibrated

The above message will be displayed until a calibration (*in vitro* or *in vivo*) or TRANSPORT function is performed (see Section 3.5).

If the Oximetry functions are attempted prior to completion of self-initialization, the following message will be displayed upon pressing the **SvO₂** key:

SvO2 not ready. Please Wait

- 7. To set time and date, press the SETUP key. Select either non-military or military (12 or 24 hour) clock using the CHANGE key. Press SET TIME on the touch bar and use the CURSOR key to select time or date. Input the current information using the touch bar. Press HOME to return to the HOME screen.
- ➤ NOTE: If a language other than English (U.S.) is selected, the date must be input as day/month/year; otherwise, it is input as month/day/year. If the military clock is selected, the time must be input in the military format (i.e., 11:00 p.m. must be input as 23:00).
- ▶ NOTE: If power is lost for any reason, for less than 60 seconds, the Vigilance will attempt to start CCO data collection if CCO was running when power was lost and will attempt to recall SvO₂ calibration data from the optical module if SvO₂ was calibrated when power was lost.

3.1.3 FUNCTION KEY FEATURES

3.1.3.1 CCO (stopped/running) Key

Pressing **CCO** initiates or terminates continuous cardiac output (CCO) monitoring. The key gives the status of the CCO at all times. It indicates CCO running during operation and CCO stopped when CCO is off. Once CCO monitoring is terminated, the large CCO display in the upper left corner will be removed, but time continues to be noted on the graph. The last CCO value is displayed with the time when monitoring was stopped. Once

CCO monitoring is resumed, the trend graph will start displaying CCO trend data, and a break in the trend line indicates when monitoring was interrupted.

If the *Vigilance* monitor is configured for CEDV monitoring, pressing the CCO (stopped/running) key also initiates or terminates continuous end diastolic volume (EDV) monitoring. Once CCO/EDV monitoring is terminated, the large EDV display on the left side will be removed, but time continues to be noted on the graph. The last EDV value is displayed with the time when monitoring was stopped. Once CCO/EDV monitoring is resumed, the trend graph will start displaying EDV trend data, and a break in the trend line indicates when monitoring was interrupted.

3.1.3.2 TREND Key

The **TREND** key allows for configuration of the graph display area as well as allowing the user to mark the time of occurrence of clinically and functionally significant events.

To set the trend graph time interval displayed on the screen, press **TREND**, then select from the various time intervals from 30 minutes to 24 hours by pressing the touch bar.

To view trend data in time periods outside the current trend screen, press the <---- and ----> touch bar keys. The time period displayed will be adjusted by the currently selected time interval.

To select the parameters to be plotted (three maximum), press **SELECT GRAPH** on the **TREND** screen and scroll through selections by using the touch bar.

NOTE: To select indexed parameters for trending (i.e. CCI, EDVI), you must first called the INDEXED option for the desired parameter on the **SETUP** screen (see Section 3.1.3.4, SETUP).

To display the selected parameters, press the **HOME** key. The trend data associated with the left axis is displayed using a thick high intensity curve. The trend data associated with the left side of the right axis is displayed using a thick low intensity curve. The trend data associated with the right side of the right axis parameter is displayed using a thin low intensity curve. Information regarding parameter range and alarm limits is displayed on the axis of the respective graph. Only CCO, CCI, EDV, EDVI, and SvO₂ can be plotted on the trend graph.



→ NOTE: When selecting a parameter for a particular graph, the user may select the vertical scale from the following ranges:

Parameter	Ranges					
CCO (L/min)	0-20	0-16	0-12	0-6	0-4	2-8
CCI (L/min/m²)	0-20	0-16	0-12	0-6	0-4	2-8
EDV (ml)	50-150	50-250	100-300	200-500	100-600	0-800
EDVI (ml/m²)	50-150	50-250	100-300	200-500	100-600	0-800
SvO ₂ (%)	0-100	50-80	50-100	30-60	20-90	

The most recent trend value is indicated by a flashing "C" for CCO/CCI, "S" for SvO_2 and "E" for EDV/EDVI. When a non-English language is selected, the flashing letter displayed is the first letter of the non-indexed parameter.

The Vigilance Monitor logs and displays certain user selectable (manually entered) and automatically recorded events. Event labels are displayed in the trend area on the **HOME** screen at the time the event occurs or is entered. If two or more events occur simultaneously, the first manually entered event selected is displayed. A manually entered event is always displayed before an automatic event, while automatic events are displayed by priority (as listed below). To manually mark an event, access the **EVENTS** menu by pressing the **TREND** key and then the **EVENTS** key. Select the appropriate event label by pressing the touch bar. Press the touch bar a second time prior to pressing the **HOME** key if that event is not to be recorded. Events and their labels are as follows (these labels will be different when a non-English language is selected):

Manually Entered Events	<u>Label</u>
Drug	D
Arrhythmia	A
Ventilator	V
Fluid	F
Nurse	N
Suction	S
Miscellaneous	M
Automatic Events	<u>Label</u>
In Vitro Calibration	I
In Vivo Calibration	С
Update Calibration	U
Recall Data from OM	R
Auto Zero Error	Z
Edwards Lifesciences	

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Light out of Range	L
Draw Blood	d
OM Disconnect	O
Bolus TD	В

Pressing the **HOME** key or **EVENT REVIEW** key will save the selected events and mark the trend graph. Once saved, an event cannot be erased or changed. When events occur simultaneously or such that the event markers would occupy the same space on the trend graph, only the oldest occurring event will be displayed.

All events are recorded in the **EVENT REVIEW** screen, 32 of which can be stored for review at any one time. When 32 events have occurred, the most recent event will replace the oldest event. To review the stored events, press the **EVENT REVIEW** key, then press **PAGE UP** or **PAGE DOWN** on the touch bar to scroll through the event listing.

3.1.3.3 PATIENT DATA Key

Specific patient parameters may be entered to obtain derived hemodynamic and oxygenation measurements. Pressing the **PATIENT DATA** key displays the cardiac profile parameters. To enter data for the oxygenation profile, press the **OXYGEN PROFILE** key. To enter data for height, weight or body surface area information, press the **Ht/Wt/BSA** touch bar key.

Table 3-1. Patient Data Calculations

By Manually Entering:	The Monitor Will:
Height (in. or cm) Weight (lbs or kg)	Calculate body surface area, display cardiac index (L/min/m²) and end diastolic volume index (ml/m²) and allow other indexed parameters to be computed and displayed.
Mean Arterial Pressure (MAP)	Calculate and display systemic vascular resistance (SVR).
Central Venous Pressure (CVP)	SVR WILL NOT be automatically updated as CO changes in the patient data screen.
Mean Pulmonary Artery Pressure (MPAP)	Calculate and display other hemodynamic parameters.
Pulmonary Artery Wedge Pressure (PAWP)	
• Heart Rate	
Arterial Oxygen Saturation	Calculate and display oxygen delivery, oxygen consumption and other oxygenation parameters.

- → NOTE: For hemodynamic and oxygenation equations, refer to Appendix B.
- ➤ NOTE: Drived parameters in the Oxygenation Profile screen are calculated from standard equations that use mixed venous oxygen staturation as the SvO₂ value.

To enter or change a patient parameter, press **EDIT** and move the cursor by pressing the **CURSOR** key. Use the touch bar to enter a new value. To recalculate the derived parameters, press the **CALC** key and the monitor will update the displayed profile. Pressing the **HOME** key will also update the information if the values are manually entered, and return you to the **HOME** screen. The time and date displayed on the top line of the patient profile indicate the time when the information was last updated. Unlike parameters displayed on the left side of the **HOME** screen, the profile parameters are not automatically updated as the values change.

The *Vigilance* allows editing of CCO, CCI, MAP, CVP, MPAP, PAWP, SaO₂, and HR while in the Patient Data Screen. When HR is edited the EDV, EDVI, ESV, ESVI and EF parameter values are blanked. Derived parameters using edited data are updated when the **CALC** key is pressed. An asterisk indicates the continuous or slaved data field was edited and the data has been overwritten. The asterisk remains on the screen until the data field is cleared. Clear the current data field by pressing the **CLEAR** key on the touch bar. After the data field is cleared, derived parameters are calculated using the continuous or slaved data. New data will only be entered into calculations by pressing the **CALC** key.

→ NOTE: Edited parameters that are not continuous or slaved will not have an asterisk attached (e.g. MPAP, PAWP).

The *Vigilance* allows editing of BSA while in the Patient Information screen. When BSA is edited, the patient's height and weight are cleared from the screen. When the patient's height or weight are cleared, the BSA is also cleared.

Derived parameters sent to the analog output ports use the continuous and slaved data. Derived parameters using edited data are not sent to the analog output ports.

- → NOTE: If you access the patient profile and do not change (EDIT) any values or the values are imported from external devices, pressing the HOME key will not update the derived parameters.
- ➤ NOTE: Input parameters common to the CARDIAC PROFILE and OXYGENATION PROFILE screens are automatically updated when input on either of the two screens.

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- → NOTE: The **CURSOR** key moves to parameters that can be edited.
- → NOTE: Refer to Appendix A for high and low limits of patient parameters.
- ▶ NOTE: Selecting NEW PATIENT provides you with the option to erase all historic profile trend, event and bolus average data, and reset alarm limits to default settings. New patient parameters for each profile may then be entered.

3.1.3.4 SETUP Key

The **SETUP** key allows for changes in the **HOME** screen display format. The **SETUP** key also allows you to set the system time and date, and to configure the monitor for input and output functions, diagnostics, and demonstration functions.

Variable: May be displayed as: Language English (US), English (British), French, German, Italian or Spanish °C. °F Temperature Units International Units No - mmHg, dn-s/cm⁵, g/dL Yes - kPa, kPa-s/L, mmol/L Time Format Military, non-military Speaker Volume Varies from low to high Patient Parameters: Measured variable or indexed to body CCO, SVR, EDV, ESV, surface area

Table 3-2. Setup

To make a change in any of the variables, press **SETUP** then use the **CURSOR** key to scroll through the variables. Press **CHANGE** to toggle between the choices. The current time and date may also be entered by selecting **SET TIME** using the touch bar.

Selecting **SET TIME** on the **SETUP** screen allows you to change the monitor's time and date. Using the **CURSOR** key to select the desired variable, the current information can be entered via the touch bar. The *Vigilance* Monitor will continue to store time and date when power is off

→ NOTE: If English (US) is selected, date is displayed as (month/day/year). Otherwise, the date is displayed as (day/month/year).

➤ NOTE: If a patient parameter that is indexed to body surface area has been selected for display and body surface area is not available, the indexed patient parameter will not be displayed. To display an indexed patient parameter, the patient's height and weight must be entered using the **PATIENT INFORMATION** screen.

The **PATIENT INFORMATION** screen is displayed when CO/CCO, EDV/ESV, SV or SVR is selected for **INDEXED** and BSA is not available when exiting the **SETUP** screen. The following message is displayed to the user requesting the patient information:

You selected indexed parameters. Please enter information above.

Press **CURSOR** to select the patient's height and weight or BSA. Use the touch bar to enter the new value.

To calculate BSA, the patient's height and weight must be entered. Patient BSA can be manually entered without height and weight. Press **CURSOR** to select BSA and use the touch bar to enter the new value. Press **RETURN** to return to the **HOME** screen.

If height and weight or BSA information is not entered into the **PATIENT INFORMATION** screen, indexed patient parameters will not be displayed. To enter the patient's height and weight or BSA at a later time, press the **PATIENT DATA** key from the **HOME** screen, then press the **Ht/Wt/BSA** touch bar key. Use the **CURSOR** key to select the desired parameter and input the new values using the touch bar.

▶ NOTE: Qxygenation derived parameters in the Small Numeric Display Area are calculated from standard equations that use mixed venous oxygen staturation as the SvO₂ value.

Selecting the **CONFIGURE PARAMETERS** on the **SETUP** screen allows you to configure the Small Numeric Display Area. To configure the Small Numeric Display Area, select the Group number desired on the touch bar keys, and press **HOME**. The parameter group selection will be displayed on the **HOME** screen from that point forward.

Selecting **SYSTEM CONFIG** on the **SETUP** screen displays the monitor's software versions. Catheter model and serial numbers for the current CCO catheter connected are also displayed (non CCO catheters will not have this information displayed).

ANALOG INPUT

To configure the Analog Input Ports to receive signals from an optional instrument, select the touch bar keys: **PORT 1, PORT 2, PORT 3** or **PORT 4**. When any of these touch bar keys are pressed the corresponding port information is displayed. The order of the

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input fields are as follows: Parameter, Voltage Range, Low Voltage Value, and High Voltage Value. The **CAL A/D** key calibrates these voltage settings, if necessary.

NOTE: The CAL A/D key should only be used by properly trained personnel. See Section 3.8.1 for a detailed description of connecting the *Vigilance* Monitor to analog input devices.

ANALOG OUTPUT

To configure the Analog Output Ports to send signals to an optional instrument, select **PORT 1** or **PORT 2** touch bar keys. When any of these touch bar keys are pressed the corresponding port information is displayed. See Section 3.8.2 for a detailed description of connecting analog output devices to the *Vigilance* Monitor.

DIGITAL PORTS

The touch bar keys **COM 1** and **COM 2** are for use with selected optional devices (for example: printer). Other serial port parameters can be changed by using the **CURSOR** to select them. Default settings are already programmed. See Section 3.8.3 for a detailed description of connecting digital devices to the *Vigilance* Monitor.

DEFAULTS

This key allows you to set the selectable alarm limits, display settings and communication port settings to original factory conditions. Patient data and trend information will be erased when these settings are re-established. See Appendix C for factory default settings.

DIAGS

This key provides access to the Diagnostics Screen that displays the cross correlation curves of the CCO run data. It also displays the STAT value and SNR (Signal-to-noise ratio) value for the run data.

DEMO

With a password, this key allows the operator to configure the instrument for demonstration purposes. The monitor will not operate in this mode with a catheter or optical module attached. A "DEMO" label will appear above the **CCO** key when the monitor is in this mode.

❖ WARNING: DO NOT USE THE DEMO MODE IN A PATIENT CARE SETTING TO AVOID POSSIBLE CONFUSION WITH PATIENT MEASUREMENTS.

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3.1.3.5 ALARMS Key

To change the limits, press **ALARMS** and select the desired parameter via the touch bar. Using the **Hi/Low** key, select the limit to be changed and enter the desired value using the touch bar. To change the other limit, use the same procedure (see Appendix C for default alarm settings).

→ NOTE: The high and low alarm limits cannot be set to the same value.

To turn the alarms off, select the **ALARMS ON/OFF** key in the **ALARM** screen. **OFF** disables both the audible and visual (English US only) alarm signals. In situations where the alarms are turned OFF, a "No Alarms" icon (shown below) will appear on all screens while the alarms are suspended. When the language option is not set to English (US), and the alarms have been turned off, a 3 second tone will sound every 3 minutes to indicate that alarms are off.

"No Alarms" icon: 🔉

→ NOTE: Alarms may be re-enabled upon instrument powerup and pressing the SETUP key in English (US).

When the alarm function is ON and the monitored parameter is outside the desired limits, audible and visual indicators will be activated. The audible indicator can be temporarily disabled for two minutes using the orange **ALARM SILENCE** button. The **ALARM SILENCE** icon (shown below) will continue to be displayed until the alarm condition is corrected, the limits are changed, or the alarm function is turned OFF.

ALARM SILENCE icon: 🛆

3.1.4 STANDARD OPERATING KEYS

3.1.4.1 HOME

This key returns the monitor to the initial or **HOME** screen from any existing screen. In most situations, the **HOME** key will save the data or instrument configuration at the time it is pressed. The **HOME** key is similar to the **ENTER** key on a personal computer.

3.1.4.2 CURSOR

This key allows you to select from the available choices in any chosen operating mode. It generally moves downward and/or to the right, and highlights the chosen entry. Highlighted entries can then be modified using other keys.

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3.2 Continuous Cardiac Output Monitoring

3.1.4.3 CHANGE

This key cycles among options for a highlighted function that has been previously selected using the **CURSOR** key.

3.1.4.4 RETURN

This key allows you to return to the first screen of a selected function. For example, in the BOLUS CO mode, the **RETURN** key returns you to the initial **BOLUS CO** screen.

3.2.1 STANDARD CCO MONITORING

- 1. Attach the catheter end of the patient cable to the appropriate catheter connectors.
- 2. Verify that the catheter is properly inserted into the patient.
- ▲ CAUTION: Prior to catheter insertion, refer to directions for use provided with each catheter for complete description, instructions, warnings, cautions, and specifications.

When the system is properly connected, the following message will be displayed:

Press CCO Key to begin CCO monitoring

3. Press the **CCO** key. The instrument will begin the measurement process as indicated by the status of 'running' underneath CCO and by displaying the following screen message:

Collecting CCO data . . .

After approximately three to six minutes, when sufficient data have been obtained, a CCO value will appear on the left of the display.

- 4. CCO data will be plotted on the trend graph. A flashing "C" indicates the most recent CCO value. When a non-English language is selected, the flashing letter displayed is the first letter of the non-indexed parameter. As new CCO values become available, the digital display will be updated (approximately every 60 sec), and a point will be plotted on the graph.
- 5. If you choose to stop CCO monitoring, press the **CCO** key. The status will indicate the stopped mode of operation. The large digital value for CCO will be removed from the display. The digital value will be replaced by the last CCO value computed with a time stamp indicating when monitoring was stopped. If CCO monitoring is resumed, a gap will appear in the plotted



trend indicating the time period when monitoring was interrupted.

6. In some situations where patient conditions create large changes in pulmonary artery blood temperature over several minutes, the monitor may take longer than 6 minutes to obtain an accurate CCO measurement. In these cases, the following alert message will appear 6 minutes after monitoring has commenced:

ALERT CCO: Signal Adapting - Continuing

If the condition has not cleared in 9 minutes (a total of 15 minutes after monitoring began), the following message will appear:

ALERT CCO: Unstable Blood Temp. - Continuing

In either case, the monitor will continue to function and no operator action is required. When CCO measurements are obtained, the alert message will be removed and the current CCO value will be displayed and plotted.

In cases where a CO measurement takes longer than 30 minutes to obtain after monitoring was intiated, the following message will appear:

FAULT CCO: Thermal Signal Loss

CCO monitoring will then be terminated. This condition could result from migration of the catheter tip into a small vessel preventing the thermistor from accurately sensing the thermal signal. Check catheter position and reposition the catheter, if necessary. After verifying patient status and catheter position, CCO monitoring may be resumed by pressing the **CCO** key.

7. When CCO monitoring is in progress, updating of the CCO measurement may be delayed by unstable PA blood temperature. If the CCO value is not updated for 6 minutes, the following message will appear:

ALERT CCO: Unstable Blood Temp. - Continuing

The last CCO value and measurement time will be displayed in place of the large digital CCO value in the upper left of the display. No operator action is required. When sufficient data are available, the CCO value will again be displayed.

If the above condition has not cleared in 14 minutes (a total of 20 minutes from the time the CO value was last updated), the following message will appear:

FAULT CCO: Thermal Signal Loss

CCO monitoring will then be terminated. This condition could result from migration of the catheter tip into a small v e s s e l preventing the thermistor from accurately sensing the thermal signal. The operator should check catheter position and reposition the catheter, if necessary. After verifying patient status and catheter position, CCO monitoring may be resumed by pressing the **CCO** key.

8. While in operation, the monitor will store up to 72 hours of trend data. If monitoring continues beyond 72 hours, the most recent data will be added to the trend, and the oldest data removed.

When power is lost, the monitor retains the last eight (8) hours of information. If power is immediately restored, those eight hours of information will be retained and displayed. As time passes without power, however, an equal amount of data is lost (i.e. after 8 hours, all 8 hours of retained data is lost). The monitor will also store any specific selections made regarding graph selections, etc., as well as user-entered patient data.

If power is restored within 60 seconds, the *Vigilance* will attempt to start CCO data collection if CCO was running when power was lost. If the instrument was configured for CEDV, EDV data collection will also resume. The monitor will also attempt to recall SvO₂ calibration data from the optical module if SvO₂ was calibrated when power was lost.

❖ WARNING: CCO MONITORING SHOULD ALWAYS BE DISCONTINUED WHEN BLOOD FLOW AROUND THE THERMAL FILAMENT IS STOPPED OR REDUCED. CLINICAL SITUATIONS WHERE CCO MONITORING SHOULD BE DISCONTINUED INCLUDE, BUT ARE NOT LIMITED TO: TIME PERIODS WHEN A PATIENT IS ON CARDIOPULMONARY BYPASS, PARTIAL WITHDRAWAL OF THE CATHETER SO THAT THE THERMISTOR IS NOT IN THE PULMONARY ARTERY, CARDIAC ARREST, OR REMOVAL OF THE CATHETER FROM THE PATIENT.

3.2.2 STAT MODE OPERATION

When monitoring continuous cardiac output, a hemodynamically unstable thermal signal may delay the *Vigilance* Monitor from displaying a CCO or CCI value after the **CCO** key has been pressed. In this event, the STAT mode may be used to present fast estimates of CCO/CCI values until such time that the thermal signal has stabilized.

- After CCO monitoring has commenced, press STAT on the blue touch bar. Ten boxes used for displaying CCO/CCI run data will appear.
- 2. The upper portion of each box displays a fast CCO/CCI estimate. The most recent run is displayed in the top left box, highlighted with a double box, and the oldest run is displayed in the bottom right box. The most recent estimate is accompanied by a time stamp. All other values are accompanied by the duration of time that has passed since that value and the most current value were first displayed. These numbers are indicated in parentheses. A countdown timer in the middle of the screen indicates when the next fast CCO/CCI estimate is expected (in seconds). If the fast estimate for a CCO/CCI run is unavailable, a blank box will be displayed.
- ➤ NOTE: The Vigilance Monitor must be configured such that CCO is an indexed parameter in order to display CCI values. If the monitor is configured for CCI and no BSA is available, the boxes will be blank. See SETUP for monitor configuration.
- → NOTE: No trend CCO or CCI value will be displayed in the large numeric display area on the left side of the screen until sufficient, time-averaged data is available.
- ➤ NOTE: When the PATIENT DATA softkey is pressed, the CARDIAC PATIENT DATA screen is displayed. STAT mode data may be manually entered in this area.
- 3. To return to the trend screen, press the **HOME** key.

3.2.3 ANESTHESIA MODE OPERATION

The Anesthesia Screen is a useful tool for viewing the trend screen and the diagnostic screen at the same time. The screen provides the trend graph as configured in the **HOME** screen, and directly below, a graph of the diagnostic CCO curves. The two diagnostic graph curves provide specific information about the process of CCO generation. They represent the time averaged SNR (signal-

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to-noise ratio) data. The darker curve is the actual representation of the patient data for CCO calculation. The lighter curve is the calculated ideal curve that represents a good SNR. The curves should be nearly superimposed when the signal is adequate. The curves are updated approximately every 60 seconds.

The following information can be obtained from the Anesthesia Screen:

BT - Blood Temperature

ST - Surface Temperature of the thermal filament CO or CI STAT - The STAT mode value of CO or CI updated approximately every 60 seconds.

SNR - The signal-to-noise ratio indicating the level of thermal noise being experienced with each updated CCO. (Range -10 to +20)

- **1.** To access the Anesthesia screen from the HOME screen or STAT screen, press **ANESTH**.
- 2. To return to the HOME screen, press **HOME**.
- 3. To return to the STAT screen, press **STAT**.
- 4. To print the displayed Anesthesia screen, press **PRINT**.

You can choose the **BOLUS CO** option for cardiac output (CO) or cardiac index (CI) measurement from the **HOME** screen via the touch bar. There are two modes for intermittent bolus CO measurement — AUTOMATIC and MANUAL.

The monitor factory default setting is the AUTOMATIC mode, which is generally the most convenient configuration. In this mode, the monitor automatically flashes an INJECT message upon achieving a baseline blood temperature. When an injection is completed, the instrument computes a value and is again ready to process another bolus injection. Up to six bolus injections can be completed in one sequence.

➤ NOTE: If an injectate temperature (IT) probe is not detected by the monitor, the following message will be displayed:

Verify IT Probe Connection

To change the mode of operation to MANUAL, press **MODE AUTOMATIC** on the touch bar, then select **MODE MANUAL**. Press **RETURN** to return to the main **BOLUS CO** screen. The MANUAL mode operation is similar to the AUTOMATIC mode except that the instrument indicates that it is in the READY state prior to an

3.3 Bolus Cardiac Output Measurement

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injection. You must press **START BOLUS** prior to each injection in the MANUAL mode.

Either cardiac output (CO) or cardiac index (CI) can be computed, displayed, and averaged in the BOLUS CO mode. CI computations are based on the most current BSA value. To alternate between CO and CI, press CO DISPLAY when CI values are displayed and CI DISPLAY when CO values are displayed.

As a factory default setting, the monitor calculates the computation constant based on the following input variables: catheter size and injectate volume. The default catheter size for computation constant selection is 8 French. Alternatively, the computation constant may be entered manually.

▲ CAUTION: Refer to the computation constant chart in Appendix D to verify that the computation constant used by the Vigilance Monitor is the same as the computation constant specified in the catheter package insert. If the constant specified by the catheter package insert does not match that used by the monitor, manually enter the desired computation constant according to the following instructions.

To manually enter the computation constant, select **BOLUS SETUP**, press **CHANGE** to select YES for the COMPUTATION CONSTANT manual entry, then press **RETURN** to return to the main **BOLUS CO** screen. To change the computation constant value, press below the label on the touch bar. Use the touch bar to enter desired constant, and press **RETURN** to effect the change.

▶ NOTE: The Vigilance Monitor does not recognize probe type (e.g. bath or in-line) when the user chooses to manually enter the computation constant (i.e. in the Computation Constant YES mode). If the probe type is changed when manual selection has been chosen, the computation constant must be changed for the corresponding probe type. If the monitor is set for automatic selection (i.e. in the Computation Constant NO mode), the computation constant is automatically determined by the monitor when the user selects the appropriate catheter size and injectate volume.

All bolus averages are recorded in the **BOLUS REVIEW** screen, 32 of which can be stored for review at any one time. When 32 averages have occured, the most recent average will replace the oldest average. To review the stored bolus averages, press the **BOLUS REVIEW** key, then press **PAGE UP** or **PAGE DOWN** on the touch bar to scroll through the bolus average listings. Bolus averages stored in the **BOLUS REVIEW** screen and plotted as

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trend dots on the **TREND** graph are not recomputed if BSA values are changed.

3.3.1 AUTOMATIC MODE

Perform the following to measure CO or CI in the AUTOMATIC mode:

 Press the touch bar beneath the BOLUS CO label displayed on the HOME screen. Injectate temperature (IT) is displayed beneath blood temperature (BT) in the lower left corner of the screen. Note the specific measurement variables (INJECTATE VOLUME, CATHETER SIZE) in the touch bar display area and change if necessary. To change a selected variable, press the touch bar beneath the appropriate label, select the correct choice, and press RETURN.

If a manually entered computation constant is to be used instead of catheter size and injectate volume, select **BOLUS SETUP** to configure the monitor to display a computation constant. The touch bar may then be used to enter the desired constant. Select **RETURN** to effect the change.

- 2. When a stable baseline blood temperature is obtained by the monitor, the INJECT message will flash, and you may proceed with a bolus injection.
- ▲ CAUTION: Sudden changes in PA blood temperature such as those caused by patient movement or bolus drug administration may cause a CO or CI value to be computed. To avoid falsely triggered curves, you should inject as soon as possible after the INJECT message appears.
 - ➤ NOTE: The STOP BOLUS key may be used to interrupt baseline blood temperature monitoring in the event that bolus measurements are discontinued. To resume baseline monitoring and bolus cardiac output measurement, press the START BOLUS key.
 - Once a bolus is injected, the thermodilution washout curve appears, a COMPUTING message is displayed, and the resultant CO measurement is displayed on the left side of the screen.
 - ➤ NOTE: If a bolus measurement is compromised, as indicated by an alert message, an "a" will appear next to the value displayed on the BOLUS CO screen.
 - 4. Subsequent determinations can be performed as desired when the INJECT message reappears.

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- → NOTE: The maximum time allowed between the appearance of the INJECT message and injection of the bolus is four minutes. If no injection is detected within this time interval, the screen returns to READY until you press START BOLUS to begin the inject cycle again.
- 5. When sufficient determinations have been made, you can press the EDIT BOLUS key to obtain an average value. The average CO or CI is displayed in the upper left corner of the screen. CO or CI is automatically averaged if the HOME key or the PATIENT DATA key is pressed. This average is indicated on the HOME screen with a dot representing the value and the time as reflected by the position on the trend.
- → NOTE: Any bolus measurement that was accompanied by an alert message will have an "a" displayed above the value on the EDIT BOLUS screen.
- ➤ NOTE: Only information displayed on the **BOLUS** screen will be transferred to the **PATIENT DATA** screen when the **PATIENT DATA** key is pressed. If CI is selected and BSA is not available then the CI data is not transferred.
- 6. All curves resulting from bolus injections are automatically utilized in determining an average value. To remove individual measurements from the displayed average, press the touch bar beneath the values to be eliminated. Only highlighted values are used to calculate the average CO. Pressing the touch bar beneath a previously eliminated measurement will again include this measurement in the average.
- Press RESUME SERIES to return to the BOLUS CO screen and press REDO SERIES to begin a new series of injections. To return to the HOME screen and display the trend graph, press HOME. Press CCO STOPPED to resume continuous monitoring, if desired.

3.3.2 MANUAL MODE

Perform the following to measure CO or CI in the MANUAL mode:

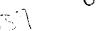
 Press the touch bar beneath the BOLUS CO label displayed on the HOME screen. Injectate temperature (IT) is displayed beneath blood temperature (BT) in the lower left corner of the screen. Note the specific measurement variables (INJECTATE VOLUME, CATHETER SIZE) in the touch bar display area and change if necessary. To change

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a selected variable, press the touch bar beneath the appropriate label, select the correct choice, and press **RETURN**.

If a manually entered computation constant is to be used instead of catheter size and injectate volume, select **BOLUS SETUP** to configure the monitor to display a computation constant. The touch bar may then be used to enter the desired constant. Select **RETURN** to effect the change.

- 2. When a baseline blood temperature is obtained by the monitor, the READY message will appear. When you are ready to inject, press the START BOLUS key, and the INJECT message will flash. You may then proceed with a bolus injection.
- → NOTE: You have a maximum of 30 seconds in which to inject following **START BOLUS**. If no injection is detected within this time interval, the screen returns to READY until you choose to resume the sequence by pressing **START BOLUS**.
- 3. Once a bolus is injected, the thermodilution washout curve appears, a COMPUTING message is displayed, and the resultant CO or CI measurement is displayed on the left side of the screen.
- → NOTE: If a bolus measurement is compromised, as indicated by an alert message, an "a" will appear next to the value displayed on the **BOLUS CO** screen.
- 4. Subsequent determinations can be performed as desired when the READY message reappears.
- 5. When sufficient determinations have been made, you can press the **EDIT BOLUS** key to obtain an average value. The average CO or CI is displayed in the upper left corner of the screen.
- NOTE: Any bolus measurement that was accompanied by an alert message will have an "a" displayed above the value on the EDIT BOLUS screen.
- 6. All curves resulting from bolus injections are automatically utilized in determining an average value. To remove individual measurements from the displayed average, press the touch bar beneath the values to be eliminated. Only highlighted values are used to calculate the average. Pressing the touch bar beneath a previously eliminated measurement will again include this measurement in the average.
- Press RESUME SERIES to return to the BOLUS CO screen and press REDO SERIES to begin a new series of injections. To



return to the **HOME** screen and display the trend graph, press **HOME**. Press **CCO** to resume continuous monitoring, if desired.

Up to six bolus injections can be completed in one sequence. If additional injections are desired (more than 6), you will be prompted to obtain an average. Then press the **REDO SERIES** key to return to the **BOLUS CO** screen and begin a new series of injections. If an average is not taken, the **HOME** screen will be displayed and the previous series of injections will be cleared.

If the **HOME** key is pressed before an average is obtained, the bolus CO data will be averaged and the **HOME** screen will be displayed. The bolus CO value will be plotted on the trend graph.

After resuming continuous monitoring, an event marker (B) will denote the change to BOLUS CO mode on the graph. The average measurement that is obtained while in BOLUS CO mode will be plotted on the graph.

3.3.3 OPTIMIZING BOLUS CO/CONTINUOUS CO CORRELATION

To optimize correlation of Bolus CO and CCO measurements, you should:

- 1. Verify correct catheter French size and injectate volume, or computation constant.
- 2. Verify proper catheter position by ensuring:
 - a) PA tracing on distal lumen port
 - b) RA tracing on proximal injectate port
 - c) 1.25 1.5 cc of air are required to obtain PAWP
 - d) correct placement by X-ray
- 3. Purge system of air.
- 4. Use correct injectate port.
- **5.** Inject 3 ml (cc) of injectate into patient for temperature equalization and ensure that there are no leaks in the system.
- **6.** Inject correct volume in rapid (10 ml (cc) within 4 seconds), smooth motion.
- 7. Ensure injectate temperature is appropriate for setup.
- **8.** Wait 1 minute between injections.
- 9. Inject randomly throughout the respiratory cycle.

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3.4 Continuous End Diastolic Volume Monitoring (EDV)

10. Edit erroneous values from average.

3.4.1 STANDARD EDV MONITORING

- 1. Attach the catheter end of the patient cable to the appropriate continuous EDV catheter connectors.
- 2. Connect the ECG slave cable's 1/4 inch miniature phone plug to the ECG Monitor input on the rear panel of the *Vigilance* unit, and connect the other end of the slave cable to the patient's bedside monitor's ECG signal output. This will provide an average Heart Rate (HR) measure to the *Vigilance* for Ejection Fraction (EF) and End Diastolic Volume calculations.
- 3. Verify that the catheter is properly inserted into the patient.
- ▲ CAUTION: Prior to catheter insertion, refer to directions for use provided with each catheter for complete description, instructions, warnings, cautions, and specifications.

When the system is properly connected, the following message will be displayed:

Press CCO Key to begin CCO monitoring.

4. Pressing the CCO key will not only start CCO monitoring, but will also start continuous EDV monitoring. The instrument will begin the measurement process as indicated by the status of 'running' underneath CCO and by displaying the following screen message.

Collecting CCO Data...

After approximately six to nine minutes, when sufficient data have been obtained, an EDV value will appear on the left of the display. The EF and averaged HR values will also appear on the bottom left corner of the display, if they were configured in the SET PARAMETER GROUP screen.

EDV data will be plotted on the trend graph. A flashing "E" indicates the most recent EDV value. When a non-English language is selected, the flashing letter displayed is the first letter of the non-indexed parameter. As new EDV values become available, the digital display will be updated (approximately every 60 sec), and a point will be plotted on the graph.

NOTE: Continuous EDV monitoring is only available in conjunction with CCO monitoring. If CCO monitoring is

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unavailable for any reason, then EDV monitoring will also be unavailable.

- 5. If you choose to stop continuous EDV monitoring, pressing the CCO key will stop both EDV and CCO. The status will indicate the stopped mode of operation. The large digital value for EDV will be removed from the display. The digital value will be replaced by the last EDV value computed with a time stamp indicating when monitoring was stopped.
- 6. In some situations where patient conditions create large changes in pulmonary artery blood temperature over several minutes, the monitor may take longer than 9 minutes to obtain an accurate EDV measurement. In these cases, the following alert message will appear 9 minutes after monitoring has commenced:

Alert CEDV: Signal Adapting - Continuing

The monitor will continue to function and no operator action is required. When EDV measurements are obtained, the alert message will be removed and the current continuous EDV value as well as the EF value will be displayed.

7. When EDV monitoring is in progress, updating of the EDV measurement may be delayed by increased PA thermal noise. If the EDV value is not updated for 8 minutes the following message will appear:

Alert CEDV: Signal Adapting - Continuing

8. In cases when the average heart rate is greater than the threshold limit (i.e. greater than 150 bpm and less than or equal to 170 bpm), the following message will appear:

Alert CEDV: Exceeding HR Threshold limit

In cases when the average heart rate goes out-of-range (i.e. less than 40 bpm or greater than 170 bpm) or when no heart rate is detected, the following message will appear:

Alert CEDV: Heart Rate Signal Loss

Continuous EDV monitoring will then be terminated. This condition could result from physiologic change in the patient's status or the loss of the ECG slave signal. The operator should

check the ECG slave cable connections and reconnect if necessary. After verifying patient status and cable connections, EDV monitoring will be resumed.

9. The accuracy of continuous EF and EDV determinations is dependent upon a regular HR or ECG slaved-in signal from the bedside monitor. If the Vigilance monitor detects a high degree of variability in the ECG within the time-averaged data, the following message will be displayed:

Alert CEDV: Irregular ECG Pattern

This condition could result from a physiologic change in the patient's status or from the unsecured leads/connections of the ECG slave signal. The operator should check the leads and the ECG slave cable connections and reposition or reconnect if necessary.

If the patient has an atrial or an atrial-ventricular (AV) pacer, the operator should assess for the presence of double sensing (for accurate HR determinations, only one pacer spike or one contraction per cardiac cycle should be sensed). In the event of double sensing, the operator should:

- Reposition the reference lead to minimize atrial spike sensing
- Select appropriate lead configuration to maximize HR triggers and minimize atrial spike sensing, and
- Assess appropriateness of milliamperage (mA) pacing levels.
- **10.** While in operation, the monitor will store up to 72 hours of trend data. If monitoring continues beyond 72 hours, the most recent data will be added to the trend, and the oldest data removed.

3.4.2 STAT MODE OPERATION

When monitoring continuous end diastolic volume, a hemodynamically unstable thermal signal may delay the *Vigilance* Monitor from displaying an EDV or EDVI value after the **CCO** key has been pressed. In this event, the **STAT** mode may be used to present fast estimates of EDV/EDVI values until such time that the thermal signal has stabilized.

- 1. After EDV (and CCO) monitoring has commenced, press **STAT** on the blue touch bar. Ten boxes used for displaying CCO/CCI and EDV/EDVI run data will appear.
- 2. The lower portion of each box displays a fast EDV/EDVI estimate (the CCO/CCI fast estimates are displayed in the upper portion of

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each box). The most recent run is displayed in the top left box (highlighted with a double box) and the oldest run is displayed in the bottom right box. The most recent estimate is accompanied by a time stamp. All other values are accompanied by the duration of time that has passed since that value and the most current value was first displayed. These numbers are indicated in parentheses. A countdown timer in the middle of the screen indicates when the next fast estimate is expected (in seconds). If the fast estimate for an EDV/EDVI run is unavailable, a blank box will be displayed.

- ➤ NOTE: The Vigilance Monitor must be configured such that EDV is an indexed parameter in order to display EDVI values. If the monitor is configured for EDVI and no BSA is available, the boxes will be blank. See SETUP for monitor configuration.
- → NOTE: No trend EDV or EDVI value will be displayed in the large numeric display area on the left side of the screen until sufficient, time-averaged data is available.
- 3. To return to the trend screen, press the **HOME** key.

3.5.1 Oximetry SETUP

3.5 Oximetry (Oxygen Saturation) Monitoring (SvO₂)

- 1. Press **SvO**₂ on the touch bar.
- Select a calibration method (IN VITRO or IN VIVO) by pressing the corresponding key. See calibration instructions below.

There are two types of calibration that can be performed:

- IN VITRO: performed before the catheter is inserted into the patient by using the calibration cup provided in catheter packaging
- IN VIVO: performed after the catheter has been inserted into the patient.
- → NOTE: For optimal accuracy, it is recommended that an in vivo calibration be performed at least every 24 hours.
- → NOTE: The **TRANSPORT** function (see Section 3.5.4) may be used to recall previous calibration data from the optical module and start Oximetry monitoring without performing a system calibration.
- ❖ WARNING: DO NOT DISCONNECT THE OPTICAL MODULE WHILE CALIBRATION AND PATIENT DATA ARE BEING TRANSFERRED FROM THE Vigilance MONITOR.

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➤ NOTE: If an oximetry catheter is being used that does not have CCO or thermodilution (TD) capabilities, the Vigilance Monitor will display the following message to indicate that the Patient CCO Cable is not connected:

Fault CCO: Check Catheter and Cable Connections.

3.5.2 IN VITRO CALIBRATION

- ▲ CAUTION: The catheter and the calibration cup must be dry for an accurate in vitro calibration. Flush the catheter lumens only after the in vitro calibration has been completed.
- ▲ CAUTION: Performing an in vitro calibration after the catheter has been inserted into the patient will yield an erroneous calibration.
 - 1. Remove section of tray lid to expose optical module connector, thermal filament connector, and thermistor connector.
 - 2. Insert the optical connector, "TOP" side up, into the optical module.
 - 3. Press SvO₂ key on the touch bar.
 - 4. Press IN VITRO CALIBRATION on the touch bar.
 - 5. If the default values of 11.5 g/dL (7.2 mmol/L) for hemoglobin and 35% for hematocrit are to be used, press the **CAL** key.
 - 6. If new (lab) hemoglobin or hematocrit values are to be entered, press CURSOR to select the desired value (either Hgb or Hct) and use the touch bar to input the new value.
 - After the correct value has been entered, press CAL. The following message will appear:

In Vitro Calibration In Progress

▶ NOTE: The user should not disconnect the catheter from the Optical module while in vitro calibration is in progress. This will cause the calibration to be invalidated.

The monitor will indicate when the calibration has been successfully completed by displaying the following message:

In Vitro Calibration OK. Insert catheter then press Start SvO₂

→ NOTE: If the system is unable to perform an in vitro calibration, the following message will be displayed:

IN VITRO CALIBRATION ERROR

The operator may press **CANCEL** to return to the **HOME** screen or press the **IN VITRO CALIBRATION** key and the *Vigilance* Monitor will restart the calibration sequence. If the error message persists, refer to the Troubleshooting Guide for further instructions.

▶ NOTE: Once a calibration has been performed, the IN VITRO CALIBRATION key is replaced by the NEW CATHETER key. When the NEW CATHETER key is pressed, the user will be asked to confirm that a new catheter is being connected. Upon confirmation, the NEW CATHETER key will revert to the IN VITRO CALIBRATION key permitting a new in vitro calibration. If the NEW CATHETER key is used, and a negative confirmation to the prompt is made, but the old catheter is still connected, SvO₂ will continue to be trended if monitoring had been previously commenced.

After the in vitro calibration has been successfully completed, prepare and insert the catheter to begin oximetry monitoring.

- 1. Remove section of catheter tray lid to expose the distal and injectate lumen hubs, as applicable.
- 2. Flush catheter.
- 3. Grasp body of the catheter at the finger depressions in the tray and lift catheter to release it from the calibration cup. Avoid pulling the catheter tip straight through the silicone gripper.
- 4. Check balloon integrity. (if applicable)
- 5. Insert catheter into the patient as described in the catheter package insert.
- 6. After the catheter is correctly positioned, press START SvO₂. The optical module will be updated with the new calibration parameters, and the *Vigilance* Monitor will return to the HOME screen.

3.5.3 IN VIVO CALIBRATION

An *in vivo* calibration is performed using blood samples drawn from the distal lumen of the catheter.

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- After the catheter is properly inserted and positioned, press SvO₂ on the touch bar.
- Press IN VIVO CALIBRATION on the touch bar. The screen will then read:

IN VIVO BASELINE SETUP IN PROGRESS.

After the baseline has been established, the SQI bar will display signal quality.

- NOTE: The user should not attempt to access another screen while the baseline setup is in progress. This will cause the calibration to be invalidated.
- NOTE: If UNSTABLE SIGNAL or WALL ARTIFACT or WEDGE messages appear during the calibration sequence, attempt to troubleshoot the problem and press IN VIVO CALIBRATION to attempt calibration again. To continue with the calibration despite the UNSTABLE SIGNAL or WALL ARTIFACT or WEDGE messages, select CONTINUE on the touch bar. The monitor will prompt the user to draw blood samples for calibration. If the calibration is to be discontinued, press CANCEL on the touch bar to return to the HOME screen. Refer to the Troubleshooting Guide (Chapter 4) for a description of causes and remedies for these particular alerts.
- Press DRAW on the touch bar.
- 4. Draw waste blood sample slowly from distal lumen.
- 5. Draw laboratory blood sample slowly (2 ml (cc) over 30 seconds).
- 6. Put blood sample on ice and send for analysis by co-oximeter.
- NOTE: While waiting for the hemoglobin/hematocrit and oximetry laboratory values, other modes may be accessed by pressing the HOME key. To return to the IN VIVO CALIBRATION screen from the HOME screen, press SvO₂ on the touch bar.
- 7. After the co-oximeter SvO₂ and hemoglobin/hematocrit values are obtained, press **CURSOR** to select the value to be entered. Enter lab HGB or Hct and SvO₂ values using the touch bar. The parameter ranges are as follows:

- NOTE: Upon entry of either a hemoglobin or hematocrit value, the *Vigilance* Monitor will automatically calculate the other value. If both hemoglobin and hematocrit values are input, the system will accept the last value entered.
- \rightarrow NOTE: When **DRAW** is selected, the SvO₂ value and the SQI value at the time the sample is drawn is displayed in the DRAW SvO₂ box on the IN VIVO CALIBRATION screen. This value is for reference only, and cannot be changed by the user. However, if no prior calibration has been performed, the DRAW SvO₂ box will not contain a value and a " - " will be displayed for SQI.
- 8. Press CAL to begin oximetry monitoring. The following message will appear:

Optical Module Update in Progress.

→ NOTE: If the operator presses CAL before entering an oximetry value and no previous in vivo calibration was performed, the user will be prompted to enter an oximetry value within the established range. If the operator presses **CAL** before entering HGB or Hct, the monitor will use values from an in vitro calibration if a previous in vitro calibration was performed.

3.5.4 TRANSPORT FUNCTION: RECALLING OPTICAL MODULE DATA

In the event that a patient needs to be transported while oximetry is being monitored, patient data (e.g. height, weight, and BSA) and system calibration information can be transferred with the patient via the optical module, eliminating the need to re-calibrate the monitor.

- With the catheter connected to the optical module, unplug the optical module cable from the Vigilance Monitor and transport it with the patient. The catheter should not be disconnected from the optical module.
- NOTE: The monitor does not need to be transferred with the patient. Another *Vigilance* Monitor may be used.
- 2. If the optical module is being connected to a new *Vigilance* Monitor, press the **PATIENT DATA** key, then select **NEW PATIENT** and confirm that data is to be deleted.

- 3. Once the patient has been transferred, re-connect the optical module cable to the *Vigilance* Monitor.
- 4. To start monitoring oximetry, return to the **HOME** screen and press **SvO₂** then **TRANSPORT** on the touch bar. The *Vigilance* Monitor will display the calibration data stored in the optical module.
- 5. Press **RECALL** on the touch bar and the optical module calibration data will be used to continue monitoring oximetry. If a new calibration is desired, return to the **HOME** screen and follow the in vivo instructions in Section 3.5.3.
- ▶ NOTE: If the optical module calibration data is greater than 24 hours old, the optical module data cannot be recalled and a new calibration will have to be performed.
- ▶ NOTE: If the system is to be re-calibrated, allow 20 minutes for the optical module to warm up.
- 6. To review patient data that was transported with the optical module, go to the **PATIENT DATA EDIT** screen and press **CALC**.

3.5.5 SIGNAL QUALITY INDICATOR (SQI)

A four level signal quality indicator (SQI) is provided to assist in proper catheter placement. The SQI level is updated every 2 seconds after SvO₂ calibration is complete. Signal Quality is displayed during IN VIVO CALIBRATION and UPDATE functions. It is recommended that calibrations be performed only when the SQI is < 3.

The SQI displays four signal levels. Those levels are:

Level 1	Normal Signal	All aspects of the signal are optimal
Level 2	Intermediate	Indicates a moderately
		compromised signal
Level 3	Poor Signal	Indicates poor signal quality
Level 4	Unacceptable	Indicates severe problem with
	•	one or more aspects of signal
		quality

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Signal quality may be compromised by the following:

- Pulsatility (e.g., wedging of catheter tip)
- Signal Intensity (e.g., kinking of catheter, blood clot, hemodilution)
- Intermittent wall contact by the catheter

It is recommended that the user troubleshoot the SvO_2 signal whenever $SQI \ge 3$. See the Troubleshooting Guide (Chapter 4) for further assistance.

- → NOTE: The SQI signal is sometimes affected by the presence of electrosurgical units. Attempt to distance electrocautery equipment and cables from the *Vigilance* system and plug the power cords into separate AC circuits if possible. If signal quality problems persist, call Edwards Technical Support for assistance.
- ▶ NOTE: To achieve optimal accuracy, it is recommended that the entered hemoglobin and hematocrit values be updated when there is a physiologic change of 6% or greater in hematocrit or of 1.8 g/dL (1.1 mmol/L) or greater in hemoglobin. A change in hemoglobin may also affect SQL Use the UPDATE function to remedy signal quality problems (see Section 3.5.6).

3.5.6 UPDATE FUNCTION

The update function can only be used if a previous calibration has been performed, or if the calibration data has been recalled from the optical module. To update calibration data:

- Press SvO₂ on the touch bar
- Pross the HGB UPDATE key
- **3.** The displayed HGB and Hct values may be used or new values entered.
- 4. Once the proper HGB and Hct values are entered, press the CAL key.

3.5.7 OPTICAL RESET

When the SQI level is continuously high, an optical reset may stabilize the signal quality. To perform an optical reset, do the following:

1. Press **SvO₂** on the touch bar.

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2. Press **OPTICAL RESET**. The following message will be displayed:

Optical Module Update in Progress

- **3.** After the intensity calibration is complete, the *Vigilance* Monitor will return to the **HOME** screen.
- → NOTE: An optical reset should only be performed after other actions to resolve the high SQI as defined in the Troubleshooting Guide (Chapter 4) has been performed.
- ➤ NOTE: The monitor will not permit an optical reset prior to performing a calibration or prior to recalling calibration data from the optical module.

3.6 Drug Calculation

3.5.8 DISABLING OXIMETRY

If an optical module is not used with the *Vigilance*, the SvO₂ information may be removed from the display. The displayed SvO₂ information may be removed by de-selecting SvO₂ in the **TREND** screen. When SvO₂ is de-selected as one of the trend graphs, the SvO₂ value, the SQI and the graphical data is removed from the display. All SvO₂ faults, alerts, notify messages and alarms are disabled when oximetry is de-selected. All other information, such as CCO and SVR, is displayed in the usual manner. The SvO₂ touch bar remains displayed when SvO₂ is deselected. If the SvO₂ touch bar is pressed, the following help message will appear:

SvO2 processing unavailable. Please configure on TREND graph.

Oximetry information may be displayed by selecting SvO_2 as a trend graph in the **TREMP** stream Select SvO_2 to reconfigure SvO_2 on the **HOME** display, when SvO_2 is re-selected, the SvO_2 information is re-displayed. All SvO_2 faults, alerts, notify messages and alarms are re-enabled when SvO_2 is re-selected.

In this mode, the *Vigilance* system can calculate infusion rate, dosage, drug amount or solution volume from the parameters which are entered.

3.6.1 DRUG TITRATION

Derived parameters for drug titration are calculated from data which is entered by the user. The *Vigilance* system will calculate the desired values based on one of the following formulas:

$$r = \frac{(dw) (W) (V)}{Rx}$$
Formula 1

$$r = \frac{(d)(V)}{Rx}$$
 Formula 2

where:

r = Infusion Rate

dw = Drug Administration by Weight

d = Drug Administration

W = Body Weight V = Solution Volume Rx = Drug Quantity

The following unit table identifies the units that are available for selection.

Weight	Dosage	Drug Amount	Volume	Rate
kg	mcg/kg/min	mg	ml	ml/hr
lbs	mcg/min			

Note: mcg = microgram mg = milligram

3.6.2 USING THE DRUG CALCULATION MODE

To access the drug titration screen, press the **DRUG CALC** touch bar key on the **HOME** screen, the **DRUG CALCULATION** screen will appear.

Select the parameter to input by pressing **CURSOR**. When the desired parameter is highlighted, enter the necessary data. Input the data by selecting the number using the numeric touch bar keys.

→ NOTE: Hard decimal points exist in the fields.

→ NOTE: If the weight has previously been entered to determine BSA, the weight in kilograms and pounds will appear in the screen.

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Continue to input all parameters in this manner. Press **CURSOR** after each input. When all data has been input, the desired parameter will be calculated automatically.

- ➤ NOTE: Updating the patient weight in the DRUG CALCULATION screen will not update the weight in the PATIENT DATA screen and the Optics Module will not be updated. The patient's weight will revert back to the PATIENT DATA weight upon leaving and re-entering the DRUG CALCULATION screen.
- → NOTE: If the CLEAR touch bar key is pressed, the current selected value field will be cleared and only the decimal point, if one exists in the field, will be displayed.

Compatible catheters include Edwards CCO/SvO₂ TD catheters, oximetry TD catheters, CCO TD catheters, CCO/CEDV TD catheters, CCO/SvO₂/CEDV TD catheters, CCO/SvO₂/VIP TD catheters, CCO/SvO₂/CEDV/VIP TD catheters, CCO/SvO₂/EDV/VIP TD catheters, oximetry catheters and thermodilution catheters.

▲ CAUTION: For continuous cardiac output measurement, only Edwards CCO catheters should be used with the *Vigilance* Monitor to ensure safe operation. For continuous end diastolic volume measurements only, Edwards CCO/CEDV, CCO/SvO₂/EDV/VIP or CCO/SvO₂/CEDV catheters should be used.

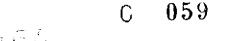
The Vigilance Monitor may be connected to a variety of other instruments to exchange patient data and print reports. Two digital communication ports (9-pin RS-232) are provided to exchange physiological data with other monitors and to export report information to a printer. Two analog output ports are provided for careling a clog signals to a chart recorder. Four analog input ports are provided to import physiological signals from other monitors.

For complete information on connecting other devices to the *Vigilance* Monitor (analog input, analog output, digital interface), please contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222.

▲ CAUTION: When connecting the *Vigilance* Monitor to external devices, refer to the external device's instruction manual for complete instructions. Verify proper operation of the system before clinical use.

3.7 Compatible Catheters

3.8 Connecting to Other Instruments



WARNING: THE ANALOG AND DIGITAL COMMUNICATION PORTS OF THE MONITOR SHARE A COMMON GROUND THAT IS ISOLATED FROM THE CATHETER ELECTRONIC COMPONENTS. WHEN CONNECTING MULTIPLE DEVICES TO THE Vigilance MONITOR, ALL DEVICES SHOULD BE PROVIDED WITH ISOLATED POWER TO AVOID COMPROMISING THE ELECTRICAL ISOLATION OF ANY OF THE CONNECTED DEVICES.

3.8.1 ANALOG INPUT DEVICES

Perform the following procedure to connect analog input devices to the *Vigilance* Monitor:

- 1. To connect a device that provides an analog signal to the *Vigilance* Monitor, select one of the four analog input connectors and plug in the cable from the analog device.
- 2. Press the following keys in sequence: **SETUP**, **SYSTEM CONFIG**, and **ANALOG INPUT**.
- 3. Use the touch bar key to select the correct analog port.
- 4. Use the **CHANGE** key to select the parameter label that the external device will be providing (MAP, CVP, SaO₂, HR (for monitors without CEDV capabilities) or NONE).
- 5. Select the voltage range (0–1, 0–5, or 0–10 volts) based on the particular device that you have connected. (Refer to the device manufacturer's manual.)
- 6. When the parameter has been selected, you will be able to see the low and high values which are the default settings for the monitor. If the actual values are different from the default values, the high and how values must be changed.
- 7. To ensure accurate operation, calibrate the *Vigilance* Monitor's analog port. Press the **CAL A/D** button to see the low value and the current value (A/D reading) that is received from the external device.
- ▲ CAUTION: Only properly trained personnel should calibrate the *Vigilance* Monitor analog ports using the CAL A/D function.
 - **8.** Send out a low voltage from the external device to the *Vigilance* Monitor (refer to the device manufacturer's manual).
 - 9. When the A/D reading is stable, press **ENTER**.
 - **10.** Repeat steps 8 and 9 to calibrate the high voltage level.

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- NOTE: Connecting to external input devices allows additional information to be displayed. For example, when MAP and CVP are available continuously from another monitor, SVR, if configured, is displayed on the **HOME** screen in the Small Numeric Display area. MAP and CVP are also displayed on the **HOME** screen, but as small numbers below all the large numeric parameters.
- → IMPORTANT: The accuracy of continuous SVR, VQI, and O_2EI depends upon the quality and accuracy of the MAP, CVP, and SaO₂ data transmitted from the external monitors. Since the MAP, CVP, SaO₂ and HR analog signal quality from the external monitor cannot be validated by the Vigilance Monitor, actual values and the values (including all derived parameters) displayed by the Vigilance Monitor may not be consistent. The accuracy of continuous SVR, VQI and O₂EI measurement, therefore, cannot be guaranteed. To aid in determining the quality of the analog signals, regularly compare the MAP, CVP, SaO₂ and HR values displayed on the external monitor to the values displayed on the Vigilance Monitor. Refer to the manufacturer's operator's manual for detailed information regarding accuracy, calibration, and other variables which may impact the analog output signal from the external monitor.

3.8.2 ANALOG OUTPUT DEVICES

Perform the following procedure to connect analog output devices to the *Vigilance* Monitor:

- 1. To connect the *Vigilance* Monitor to a device that can accept an analog signal, select one of the two analog output ports and plug in the connector.
- 2. Press the following keys in sequence: **SETUP**, **SYSTEM CONFIG**, and **ANALOG OUTPUT**.
- 3. Use the touch bar key to select the appropriate analog port.
- 4. Use the **CHANGE** key to select the patient parameter that you want to export from the *Vigilance* Monitor (CCO, CCI, SvO₂, BT, IT, ΔBT, SVR, SVRI or NONE).
- 5. Use the **CURSOR** key then the **CHANGE** key to select the voltage range: 0–1 or 0–10 volts.

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6. If the device you are connecting allows for calibration, the monitor will continuously send out a low or high voltage when either the CALIBRATE LOW or CALIBRATE HIGH key is pressed.

3.8.3 DIGITAL DEVICES

Perform the following procedure to connect digital devices to the *Vigilance* Monitor:

- The Vigilance Monitor Data Terminal Equipment (DTE) digital ports are provided by two 9-pin connectors. If the device that you are connecting to the monitor is also a DTE, then a null modem cable or adapter is required. To connect another digital device to the monitor, select one of the two digital connectors (COM 1 or COM 2) and plug in the cable from the device.
- 2. Press the following keys in sequence: **SETUP**, **SYSTEM CONFIG**, and **DIGITAL PORTS**.
- 3. Use the touch bar key to select the correct port (COM 1 or COM 2). The cursor should be positioned on the device label for that port.
- 4. Use the **CHANGE** key to select the device that has been connected (Printer, IFMout, or Flexport*). Press the **HOME** key when completed.
- 5. All device selections are listed with standard communication protocol parameters already set to default values. To change these parameters, press CURSOR to select the parameter that you wish to change and use the CHANGE key.
- → NOTE: Flexport[®] parameters cannot be changed by the user.
- **6.** The *Vigilance* Monitor supports the following communication parameters:

 Baud rate:
 1200
 2400
 9600
 19200

 Parity:
 None
 Odd
 Even

Parity: None Oct Data Bits: 7 8 Stop Bits: 1 2

Flow Control: None XON/XOFF

3.8.3.1 PRINTER FUNCTION

When **PRINT** appears as a touch bar label, the current *Vigilance* screen may be printed. Once **PRINT** is selected, allow entire screen to print prior to pressing any other keys.

For a listing of current supported printers and for proper printer setup, please contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222.

3.8.3.2 IFMOUT FUNCTION

To export parameter values to any Patient Monitor or PC that accepts the *Vigilance* IFMout protocol, select the device to be IFMout. For assistance in selecting the proper communication parameter settings contact Edwards Technical Support (see Appendix F).

► NOTE: Oximetry data that is exported via IFMount will be labeled as SvO2 on the receiving patient monitor screen.

3.8.3.3 FLEXPORT® FUNCTION

To export parameter values to a SpaceLabs Medical Patient Care Management System select the device to be Flexport[®]. Communication parameter settings are pre-set and cannot be changed. For assistance in connecting to a SpaceLabs Monitor contact Edwards Technical Support (see Appendix F).

3.9 Warnings

- → NOTE: Oximetry data that is exported via Flexport will be labeled as SvO₂ on the receiving patient monitor screen.
- WARNING: CAREFULLY READ THIS OPERATOR'S MANUAL BEFORE ATTEMPTING TO USE THE EDWARDS Vigilance MONITOR.
- * WARNING: PEEP TO THE CATHETER PACKAGE INSERT PROVIDED WITH EACH CATHETER FOR SPECIFIC INSTRUCTIONS ON CATHETER PLACEMENT AND USE, WARNINGS, CAUTIONS, AND SPECIFICATIONS.
- WARNING: DO NOT USE A DAMAGED CATHETER OR ONE WITH EXPOSED ELECTRICAL CONTACTS.
- ❖ WARNING: INACCURATE CARDIAC OUTPUT MEASUREMENTS MAY BE CAUSED BY:
 - Incorrect placement or position of the catheter
 - Excessive variation in pulmonary artery blood temperature
 - Clot formation on the thermistor
 - Anatomical abnormalities (for example, cardiac shunts)
 - Excessive patient movement

- Repeated intermittent flushes of cold fluid through the fluid lumens of the catheter
- Use of a manual blood pump
- Electrocautery or electrosurgical unit interference
- Rapid changes in cardiac output
- ❖ WARNING: IN SITUATIONS WHERE MONITORED PATIENT PARAMETERS ARE OUTSIDE THE DESIRED ALARM LIMITS, THE AUDIO ALARM WILL NOT SOUND IF THE ALARM HAS BEEN TURNED OFF OR TEMPORARILY SILENCED. DO NOT TURN OFF THE ALARMS IN SITUATIONS IN WHICH PATIENT SAFETY COULD BE COMPROMISED.
- ❖ WARNING: CCO MONITORING SHOULD ALWAYS BE DISCONTINUED WHEN BLOOD FLOW AROUND THE THERMAL FILAMENT IS STOPPED OR REDUCED. CLINICAL SITUATIONS WHERE CCO MONITORING SHOULD BE DISCONTINUED INCLUDE BUT ARE NOT LIMITED TO: TIME PERIODS WHEN A PATIENT IS ON CARDIOPULMONARY BYPASS, PARTIAL WITHDRAWAL OF THE CATHETER SO THAT THE THERMISTOR IS NOT IN THE PULMONARY ARTERY, OR REMOVAL OF THE CATHETER. FROM THE PATIENT.
- ❖ WARNING: EXPLOSION HAZARD! DO NOT USE THE Vigilance MONITOR IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
- WARNING: TO AVOID COMPLICATIONS CAUSED BY KNOTTING, THE CATHETER SHOULD NOT BE USED SIMULTANEOUSLY WITH ANOTHER PULMONARY ARTERY CATHETER.
- * WARNING, DO NOT USE THE DEMO MODE IN A PATIENT CARE SETTING TO AVOID POSSIBLE CONFUSION WITH PATIENT MEASUREMENTS.
- * WARNING: IMPROPER USE OF THE Vigilance MONITOR COULD PRESENT A HAZARD TO THE PATIENT. CAREFULLY READ THE WARNINGS SECTION OF THIS MANUAL BEFORE USING THE INSTRUMENT.
- ❖ WARNING: THE ANALOG AND DIGITAL COMMUNICATION PORTS OF THE MONITOR SHARE A COMMON GROUND THAT IS ISOLATED FROM THE CATHETER INTERFACE ELECTRONICS. WHEN CONNECTING MULTIPLE DEVICES TO THE Vigilance MONITOR, ALL DEVICES SHOULD BE

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PROVIDED WITH ISOLATED POWER TO AVOID COMPROMISING THE ELECTRICAL ISOLATION OF ANY OF THE CONNECTED DEVICES.

- ❖ WARNING: THE Vigilance MONITOR CONTAINS NO USER-SERVICEABLE PARTS. REMOVAL OF THE COVER OR DISASSEMBLY WILL EXPOSE HAZARDOUS VOLTAGES. TO AVOID INJURY OR INSTRUMENT DAMAGE, DO NOT DISASSEMBLE OR SERVICE THE INSTRUMENT UNLESS YOU ARE QUALIFIED TO DO SO.
- ❖ WARNING: FOR PROTECTION AGAINST FIRE, REPLACE THE FUSE WITH ONLY ONE OF THE SAME TYPE AND RATING.
- ❖ WARNING: THE Vigilance MONITOR IS INTENDED FOR USE ONLY AS AN ADJUNCT IN PATIENT ASSESSMENT. THIS INSTRUMENT MUST BE USED IN CONJUNCTION WITH PATIENT CLINICAL SIGNS AND SYMPTOMS.
- ❖ WARNING: TO AVOID SHOCK OR FIRE HAZARD, DO NOT SOAK OR IMMERSE THE *Vigilance* MONITOR, PROBES, OR CABLES IN ANY LIQUID SOLUTION. DO NOT ALLOW ANY FLUIDS TO ENTER THE INSTRUMENT.
- WARNING: CONDUCT PERIODIC INSPECTIONS OF ALL CABLES FOR DEFECTS. DO NOT STORE CABLES TIGHTLY COILED.
- ❖ WARNING: TREAT THE OPTICAL MODULE WITH EXTREME CARE.
- **❖ WARNING:** DO NOT OBSTRUCT THE *Vigilance* MONITOR'S VENTILATION OPENINGS.
- ❖ WARNING: DO NOT EXPOSE THE Vigilance MONITOR TO EXTREME TEMPERATURES.
- ❖ WARNING: DO NOT USE THE Vigilance MONITOR DURING MRI SCANNING.
- ❖ WARNING: DO NOT DISCONNECT THE OPTICAL MODULE WHILE CALIBRATION AND PATIENT DATA ARE BEING TRANSFERRED FROM THE *Vigilance* MONITOR.

4

TROUBLESHOOTING GUIDE

4. Resolving Monitoring Problems

This section discusses possible monitoring difficulties, their possible causes, and suggested resolutions. Table 4-1 on the next page contains a troubleshooting checklist to assist you in identifying and correcting possible problems. The checklist is followed by a section that describes displayed fault and alert messages, and alarm conditions.

If a problem persists after following the indicated suggestions, you should discontinue operation and contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222.

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4.1 Troubleshooting Checklist

Table 4-1. General Troubleshooting Checklist

Problem	Possible Cause	Solution
Instrument does not power on	AC power not connected, Defective fuse	Connect to AC power Replace fuse as marked
Monitor screen is blank	System malfunction	 Turn power off and on again If problem persists contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
Monitor displays message: Main processor not responding or Please recycle power to restore system	System malfunction	 Turn power off and on again If problem persists contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
Monitor displays message: SvO ₂ processing unavailable	• SvO ₂ subsystem malfunction	 Turn power off and on again If problem persists contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
Monitor displays message: CCO processing unavailable	CCO subsystem malfunction	 Turn power off and on again If problem persists contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
Monitor displays message: Bolus CO unavailable	Bolus <u>CCO</u> subsystem malfunction	 Turn power off and on again If problem persists contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222

Table 4-1. General Troubleshooting Checklist (continued)

Continuous Cardiac Output (CCO) measurements do not agree with Bolus Cardiac Output measurements	 Instrument configured incorrectly Faulty thermistor or injectate probe connection Unstable baseline temperature affecting bolus CO measurements 	 Verify that computation constant, injectate volume, and catheter size have been correctly selected Use "iced" injectate and/or 10 ml (cc) injectate volume to create large signal
Analog port connections with peripheral monitoring equipment produce questionable communications	Incomplete connections External monitor needs calibration	 Check cable connections Check analog port setup (analog port calibration) Check external monitor's output signals
Digital port connections with peripheral monitoring equipment produce questionable communications	Incomplete connectionsExternal monitor needs calibration	 Check cable connections Check serial port setup, Check external monitor's calibration

4.2 Displayed Messages

The message display area is located in the top center of the screen. Three types of messages that may be displayed in this area are: Faults, Alarms, and Alerts. Messages appear in the following order of priority: 1) Faults, 2) Alarms, 3) Alerts.

A message is cleared from the screen if:

- The condition has been resolved.
- The user presses CCO key and the condition is no longer in effect.
- Another message of higher priority or a new message of the same priority needs to be displayed.

In the last situation, the older message will not be shown due to limited display space. Once the new condition has been cleared, if the original condition still exists, the older message will reappear.

In addition, SvO_2 calibration warning messages may be displayed in the trend graph area. These warnings indicate difficulties with SvO_2 calibration.

4.2.1 FAULT MESSAGES

Fault messages indicate situations in which the system cannot operate properly and are accompanied by a single beep tone. Fault messages will terminate CO or oximetry monitoring. Correction of a fault condition is necessary to resume CO or oximetry monitoring in the present mode. In some cases, fault conditions that prevent CCO monitoring will not prevent bolus CO or oximetry monitoring. For example, **Check Thermal Filament Connection** is a fault message in CCO mode, but will not affect BOLUS-CC or oximetry mode operation.

4.2.2 ALARM CONDITIONS

Alarm conditions occur for selected patient parameters when the calculated value is outside the range determined by the high and low limits. The alarm function must be ON to generate the audible and visual indicators. The audible indicator consists of a repeating sequence of three rapid tones. Numerical values of the alarming patient parameter are repeatedly flashed to provide a visual indicator. The alarm will continue until the condition is cleared, the **ALARM SILENCE** key is pressed, the limits are changed, or the alarms are turned off.

4.2.3 ALERT MESSAGES

Alert messages are intended to provide help in qualifying the measurement results. These messages appear on the screen without auditory notification. In most cases, no corrective action is required by the operator when an alert message is displayed.

4.2.4 SvO₂ CALIBRATION WARNING MESSAGES

Warning messages pertaining to SvO_2 system calibration are displayed in the trend graph area when oximetry monitoring is available and system calibration may be compromised. Depending on the nature of the warning condition, the user may continue with the calibration sequence, troubleshoot the problem and attempt another system calibration, or cancel the calibration and return to the **HOME** screen.

4.3 Fault Message Summary

The following summaries provide a quick-reference to the displayed messages. Refer to Tables 4-2 to 4-8 for detailed information of Fault, Alert, and Warning messages that include possible causes and suggested corrective actions.

4.3.1 CCO MODE (see Table 4-2 for detail)

- 1. Thermal Filament, Use Bolus Mode
- 2. Catheter Memory, Use Bolus Mode
- 3. Catheter Verification, Use Bolus Mode
- 4. Check Catheter and Cable Connections
- 5. Blood Temp Out of Range (< 31 or > 41)
- 6. Check Thermal Filament Connection
- 7. Uneck Thermal Filament Position
- 8. Check Thermistor Connection
- 9. CO is less than 1.0 L/min
- 10. Thermal Signal Loss
- 11. CCO Signal Processor, Use Bolus Mode
- 12. CCO Not Available, Use Bolus Mode
- 13. CCO Thermal Filament, Use Bolus Mode
- 14. CO: Not Responding

15. Thermal Element, Use Bolus Mode

4.3.2 OXIMETRY

(see Table 4-3 for detail)

- 1. OM2 Memory
- 2. Auto Zero
- 3. Light Range
- 4. Out of Range
- 5. Red/IR Transmit
- 6. OM Disconnected
- 7. EPROM
- 8. RAM
- 9. Offset
- 10. Gain
- 11. SvO₂ Not Responding
- 12. SvO₂ Processing Unavailable

4.3.3 BOLUS CO MODE (see Table 4-4 for detail)

- 1. Check Thermistor Connection
- 2. Injectate Too Warm, Check Probe
- 3. Bolus CO Unavailable

4.4 Alert Message Summary

4.4.1 CCO MODE (see Table 4-5 for detail)

- 1. Signal Adapting Continuing
- 2. Unstable Blood Temp. Continuing
- 3. Electrical Interference

4.4.2 OXIMETRY

(see Table 4-6 for detail)

1. SQI = 4

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- **4.4.3 CEDV MODE** (see Table 4-7 for detail)
 - 1. Signal Adapting Continuing
 - 2. Exceeding HR Threshold Limit
 - 3. Heart Rate Signal Loss
 - 4. Irregular ECG pattern

4.4.4 BOLUS CO MODE (see Table 4-8 for detail)

- 1. Curve Not Detected
- 2. Extended Curve
- 3. Irregular Curve
- 4. Warm Injectate
- 5. Unstable Baseline
- 6. Electrical Interference

4.5 Warning Message Summary

4.5.1 OXIMETRY

(see Table 4-9 for detail)

- 1. In Vitro Calibration Error
- 2. Wall Artifact or Wedge
- 3. Unstable Signal

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Table 4-2. Fault Messages, CCO Mode

Table 4-2. Tault Messages, CCO Mode			
Displayed Message	Possible Cause	Suggested Action	
1. Thermal Filament, Use Bolus Mode	Thermal filament measurement error	 Use BOLUS CO mode Contact Edwards Technical Support Replace catheter for 	
		CCO measurement	
2. Catheter Memory, Use Bolus Mode	Poor catheter connectionCable malfunctionThermal filament error	Check catheter and cable connections Change patient cable Replace catheter for	
		Replace catheter for CCO measurement Use BOLUS CO mode	
3. Catheter Verification, Use Bolus Mode	 Cable malfunction Thermal filament error Catheter connected is not an Edwards catheter 	 Change patient cable Use BOLUS CO mode Verify that catheter is an Edwards catheter for CCO measurement 	
4. Check Catheter and Cable Connections	Catheter connections (thermal filament and thermistor) not detected	 Check catheter cable and catheter connections Disconnect thermistor and thermal filament connection and check for bent pins, etc. 	
5. Blood Temp Out of Range (< 31 or > 41)	 Blood temperature is less than 31° C or greater than 41° C 	 Verify that catheter is properly positioned in the pulmonary artery Wait for blood temperature to be within range 	
6. Check Thermal Filament Connection	 Monitor cannot sense the thermal filament Catheter connected is not an Edwards CCO catheter 	 Verify that catheter is connected to patient cable Verify that catheter is an Edwards catheter for CCO measurement Use BOLUS CO mode 	

Table 4-2. Fault Messages, CCO Mode (continued)

Displayed Message	Possible Cause	Suggested Action
7. Check Thermal Filament Position	 Flow around thermal filament may be reduced Blood temperature too warm Catheter not in patient 	 Verify proper catheter position Wait for blood temp. to decrease Verify that catheter tip is properly positioned in the pulmonary artery
8. Check Thermistor Connection	 Loose thermistor connection Invalid blood temperature measurements 	 Verify that catheter thermistor is connected securely Verify that thermistor temperature is between 15–45° C
9. CO is less than 1.0 L/min	Measured CO less than 1.0 L/min	Wait for CO to increase
10. Thermal Signal Loss	Signal detected by monitor is too small to process	 Verify proper catheter position Press CCO key to resume CCO monitoring, as indicated
11. Signal Processor, Use Bolus Mode	Electrical interference (e.g., electrocautery device)	Power off and restartUse BOLUS CO mode
12. CCO Not Available, Use Bolus Mode	CCO Subsystem has malfunctioned	 Turn monitor off and restart If problem persists, call Edwards Technical Support at 1.800.822.9837 or 949.250.2222.
13. CCO Thermal Filament, Use Bolus Mode	CCO Subsystem has malfunctioned	 Turn monitor off and restart If problem persists, call Edwards Technical Support at 1.800.822.9837 or 949.250.2222.



 Table 4-2. Fault Messages, CCO Mode (continued)

Displayed Message	Possible Cause	Suggested Action
14. CO: Not Responding	Electrocautery interference has been continuous for 5 minutes	 Turn monitor off and restart Disconnect CCO cable during continuous electrocautery use at more than 5 minutes If problem persists, call Edwards Technical Support at 1.800.822.9837 or 949.250.2222.
15. Thermal Element, Use Bolus Mode	CCO Subsystem has malfunctioned .	 Turn monitor off and restart If problem persists, call Edwards Technical Support at 1.800.822.9837 or 949.250.2222.

Table 4-3. Fault Messages, Oximetry Mode

Displayed Message	Possible Cause	Suggested Action
1. OM2 Memory	Optical Module memory is dysfunctional	• Replace optical module
2. Auto Zero	 Electrocautery interference Bright light into optical module or catheter tip 	 Wait until electrocautery use is discontinued. If problem persists, call Edwards Technical Support at 1.800.822.9837 or 949.250.2222. Check optical module/catheter connections
3. Light Range	 Loose connections Optical module failure Catheter kinked or damaged 	 Check optical module connections Check for obstructed optical surface; replace optical module Perform in vivo calibration; replace catheter if damage is suspected and recalibrate the Vigilance monitor

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Table 4-3. Fault Messages, Oximetry Mode (continued)

Displayed Message	Possible Cause	Suggested Action
4. Out of Range	Calculated value outside of 0 - 99% range	• Recalibrate the Vigilance Monitor
5. Red/IR Transmit	Optical module is damaged	 Replace optical module. If problem persists, contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
6. OM Disconnected	Loose connections	Check optical module/catheter connection
7. EPROM	• SvO ₂ smart module EPROM test failed	Turn monitor off and restart
8. RAM	• SvO ₂ optical module RAM test failed	Turn monitor off and restart
9. Offset	Internal electrical problem .	 Contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
10. Gain	Internal electrical problem	• Contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
11. SvO ₂ Not Responding	 No communication between SvO₂ module and mainframe 	 Turn monitor off and restart If problem persists, contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
12. SvO ₂ Processing Unavailable	Oximetry function disabled	 Reconfigure SvO₂ by selecting SvO₂ as a trend graph in the TREND screen.

Table 4-4. Fault Messages, Bolus CO Mode

Displayed Message	Possible Cause	Suggested Action
1. Check Thermistor Connection	Loose thermistor connection	Verify that catheter thermistor is connected
	Invalid blood temperature measurements	Verify that thermistor temperature is between 15–45° C
2. Injectate Too Warm,	• Injectate temperature > 30° C or > BT	Use cooler injectate fluid
Check Probe		Replace injectate temperature probe
3. Bolus CO unavailable	No communication with the CO module	Turn monitor off and restart.
		• If problem persists, contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222

Table 4-5. Alert Messages, CCO Mode

Displayed Message	Possible Cause	Suggested Action
1. Signal Adapting - Continuing	Patient's respiratory pattern may have changed	Allow more time for the monitor to measure and display CCO
2. Unstable Blood Temp Continuing	Large blood temperature variations detected	Wait for CO measurement to be updated Minimizing patient
		discomfort may reduce temperature variations
3. Electrical Interference	 Electrocautery interference 	Wait until electrocautery use is terminated

Table 4-6. Alert Messages, Oximetry Mode

Displayed Message	Possible Cause	Suggested Action
1. SQI = 4	 Low blood flow at catheter tip or catheter tip against vessel wall 	• Reposition and/or flush catheter
	• Change in HGB/Hct values	Update HGB/Hct values using UPDATE function
	Catheter kinked or damaged	 Check catheter for kinking and recalibrate; replace catheter if required and recalibrate

Table 4-7. Alert Messages, CEDV Mode

Displayed Message	Possible Cause	Suggested Action
1. Signal Adapting - Continuing	Patient's respiratory pattern may have changed	Allow more time for the monitor to measure and display EDV.
	• Use of some types of Sequential Compression Devices	Turn SCD cooling system off temporarily.
	(SCDs)	 If problem persists, contact Edwards Technical Support at 1.800.822.9837 or 949.250.2222
2. Exceeding HR Threshold Limit	 Patient's time- averaged heart rate is greater than 150 bpm but less than or equal to 170 bpm 	 Verify average HR values. Follow standard hospital protocol for reducing patient's HR below 150 bpm
3. Heart Rate Signal Loss	• Average patient's heart rate out-of-range (HR<40 bpm or HR>170 bpm)	Wait until average heart rate is within range.
	No heart rate detected Loose slave cable connections	 Verify slave cable connections between Vigilance and bedside monitor.

Table 4-7. Alert Messages, CEDV Mode (continued)

Displayed Message	Possible Cause	Suggested Action
4. Irregular ECG Pattern	 Physiologic change in patient's status Unsecured leads/connections of the ECG signal Double-sensing due to atrial or atrial-ventricular (AV) pacing 	 Follow standard hospital protocol. Reposition leads or reconnect ECG slave cable if necessary. Reposition reference lead to minimize atrial spike sensing. Select appropriate lead configuration to maximize HR triggers and minimize atrial spike sensing. Assess appropriateness of milliamperage (mA) pacing levels.

Table 4-8. Alert Messages, Bolus CO Mode

Displayed Message	Possible Cause	Suggested Action
1. Curve Not Detected	Greater than 4 minutes (AUTOMATIC mode) or 30 seconds (MANUAL mode) has passed without detection of injection	• Press START and begin injections
2. Extended Curve	Thermodilution curve slow to return to baseline Injector port in introducer Possible cardiac shunt	 Use correct injection technique Verify thermister location Ensure injectate port location is outside introducer Verify accuracy of CO measurement
3. Irregular Curve	• Thermodilution curve has multiple peaks	 Check injection technique Check thermistor location Possibly eliminate value from CO average

Table 4-8. Alert Messages, Bolus CO Mode (continued)

Displayed Message	Possible Cause	Suggested Action
4. Warm Injectate	• Injectate temperature within 8°C of blood temperature	 Use cooler injectate fluid Replace injectate temperature probe
5. Unstable Baseline	Unable to compute cardiac output	Make more injections Use MANUAL mode
6. Electrical Interference	Electrocautery interference	Wait until electrocautery use is terminated

Table 4-9. Warning Messages, Oximetry Mode

Displayed Message	Possible Cause	Suggested Action
1. In Vitro Calibration Error	 Loose connections Calibration cup wet Catheter kinked or damaged Optical module failure 	 Check optical module connections Perform in vivo calibration Perform in vivo calibration and straighten out visible kinks; replace catheter if damage is suspected Replace optical module
2. Wall Artifact or Wedge	 Low blood flow at catheter tip Catheter tip ciotted Catheter tip wedged in vessel or against vessel wall 	 Reposition catheter and recalibrate by performing in vivo calibration Try to aspirate distal lumen; if able to aspirate, flush lumen with extreme caution and reposition catheter Reposition catheter, and if SQI > 2, recalibrate monitor by performing in vivo calibration
3. Unstable Signal	 Changing SvO₂, HGB/Hct, or unusual hemodynamic values 	Stabilize patient and recalibrate monitor by performing in vivo calibration

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4.6 Cleaning the Monitor and Accessories

The surface of the *Vigilance* Monitor may be cleaned with a cloth dampened with 70% isopropyl alcohol or a non-abrasive, liquid commercial cleaner or spray disinfectant. Stronger institutional disinfectants such as chlorhexidine gluconate or glutylaldehyde may also be used. The top, bottom and front surfaces may be lightly wiped with the cloth, but the monitor screen and its accessories SHOULD NOT have liquid poured or sprayed directly on them.

- DO NOT allow any liquid to come in contact with the power connector, fuse holder, or switches, nor to penetrate connectors or openings in the chassis. If any of the foregoing does occur, DO NOT attempt to operate the monitor. Disconnect power immediately and call Edwards Technical Support at 1.800.822.9837 or 949.250.2222.
- DO NOT attempt to clean the rear panel of the monitor.
- Cleaning System Cables Decontamination of these parts can be accomplished by wiping the surfaces with specific disinfectants. Sterile alcohol preps containing 70% isopropyl alcohol can be used to clean the Patient Cable and other accessory cables.

To clean the cables with disinfectant, use sterile gauze sponges and sterile water. Moisten the cotton gauze with the disinfectant and clean the surfaces. Follow the cleansing with rinsing wipes using cotton gauze moistened with sterile water. Use sufficient rinsing wipes to remove all residual disinfectant. Complete the cleaning process by drying the surface with sterile gauze.

- Cleaning the Optical Module Sterile alcohol preps containing 70% isopropyl alcohol can be used to clean the optical module housing and the connecting cable. Sterile alcohol preps do not leave a residual film after use. The fiber optic interface of the optical module must be kept clean. The optical fibers within the oximetry catheter fiber optic connector mate with the optical fibers in the optical module. Cotton tipped applicators can be moistened using sterile alcohol preps. Apply gentle pressure when using cotton swabs to clean the optical fibers recessed within the front of the optical module.
 - Do not steam, radiation or EtO sterilize.
 - Do not immerse.

A

VIGILANCE MONITOR SPECIFICATIONS

A.1 General

Product Description: The *Vigilance* Monitor measures continuous cardiac output (CCO), continuous end diastolic volume (EDV) and Oximetry (SvO_2) when used with an Edwards Continuous Cardiac Output, Volumetric and Oximetry Catheter.

Weight		23 lbs
Dimensions	Height Width Depth	6.2 in. 12.9 in. 14.7 in.
Patient Cable	Length	8.5 ft
CRT Display System	Display Area	7.9 in. by 2.8 in.
Trend Display	Length	30 minutes to 24 hours
	Parameters (3 max.)	SvO ₂ , CCO, CCI, EDV, EDVI

A.2 Measurement Specifications

CCO Mode	Range Reproducibility*	1 to 20 L/min ±6% or 0.1 L/min, whichever is greater
	Response Time**	3–9 minutes
Oximetry (Oxygen Saturation) Mode	Range Precision†	0 to 99% ±2% at 30 to 99%
CEDV Mode	EF Range EF Reproducibility*	10 to 60% ±6% or 3 efu, whichever is greater
Heart Rate Range for EF Measurement	(Averaged over 1 run length)	40 to 150 bpm
Bolus CO Mode	Range Reproducibility*	1 to 20 L/min ±3% or 0.1 L/min whichever is greater
Blood Temperature Range		15 to 45°C, ±0.3°C (59 to 113°F)
Injectate Temperature Range		0 to 30°C, ±0.3°C (32 to 86°F)
Patient Data Profiles	Calculates derived hemodynamic and oxygenation parameters based upon entered data	

- * Coefficient of variation measured using electronically generated data
- ** 10% to 90% change, under conditions of stable blood temperature
- † Precision was tested under laboratory conditions

A.3 Patient Data Profiles

Parameter Ranges	SaO ₂	40 - 100%*
	SvO ₂	10 - 99%
;	HGB	4 - 20 g/dL (2.5 - 12.4 mmol/L)
	PaO_2	0 - 1520 mmHg (0.0 - 202.6 kPa)
	PvO ₂	0 - 1520 mmHg (0.0 - 202.6 kPa)
	MAP	0 - 500 mmHg (0.0 - 66.6 kPa)
	CVP	0 - 100 mmHg (0.0 - 13.3 kPa)
İ	MPAP	0 - 100 mmHg (0.0 - 13.3 kPa)
	PAWP	0 - 100 mmHg (0.0 - 13.3 kPa)
	HR	30 - 250 bpm**
	Height	12 - 98 in. (30 - 250 cm)
ļ	Weight	2 - 880 lbs (0.9 - 400 kg)
	BSA	0.08 - 5.02 m ²

- * 0-100% for English (US)
- ** 1-250 bpm for English (US)

A.4 Technical

System Interface	Analog Inputs (4)	Selectable span 0–1 volt, 0–5 volts, 0–10 volts >100kΩ input impedance, 1/8 in. phone jack Bandwidth = 5 Hz Resolution = 12 bits		
	ECG Monitor Input (1)	1/4 inch miniature phone plug analog cable		
	Analog Outputs (2)	Selectable span 0–1 volt 0–10 volts, 1/8 in. phone jack Bandwidth = 10 Hz Resolution = 8 bits		
	Digital I/O (2)	RS-232, programmable DE9 serial ports Maximum data rate = 19.2 Kilobaud		
• .	Touch Bar	Pressure-sensitive switch to enter numeric . data and select menu items.		
	Keypad	Five push buttons to select menu items.		
Electrical	Voltage	100 to 240 volts ac, 50/60 Hz		
	Power Consumption	180 watts, maximum		
	Fuse	UL and CSA approved, 3.0 amps, 250 volts, fast-acting F 3A/250V		

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A.5 Environmental Requirements

Operating Temperature	10 to 35°C (50 to 95°F)
Storage Temperature	-40 to 65°C (-40 to 149°F)
Operating and Storage Relative Humidity	10% to 95% non-condensing
Operating and Shipping Pressure	0 to 10,000 ft (equivalent pressure)

A.6 Accessories

A.6.1 Vigilance Monitors

The following accessories are available for use with Vigilance Monitors.

Catheters	*		
Power Cord	Model COM-2-PC		
Operator's Manual	*		
Catheter Interface Cable	Model 70CC2		
Optical Module**	Model OM2 or OM2E [†]		
In-Line Temperature Probe	Model 93522		
Bath Temperature Probe	Model 9850A		
Printer	*		
Printer Interface Cable	*		
Pressure Slave Cables	*		
ECG Monitor Slave Cables	***		
Nellcor Pulse Oximeter Slave Cables	*		

^{*}Please contact your Edwards representative, or call Edwards Customer Service at 800.424.3278 (in the US and Canada) or 949.250.2500 (outside the US and Canada).

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^{**} For models configured with SvO_2 only.

^{***} For models configured with CEDV only.

[†] For European models.

A.7 International Symbols

The following table shows the international medical equipment symbols used on the *Vigilance* Monitor with their respective meanings:

†	TYPE B EQUIPMENT - Equipment protected against electric shock.
†	TYPE BF EQUIPMENT - Equipment protected against electric shock, having an F-type isolated (floating) applied part.
	TYPE CF EQUIPMENT - Equipment protected against electric shock, having an F-type isolated (floating) applied part and intended for direct cardiac application.
<u>İ</u>	ATTENTION: Consult accompanying documents.
F 1A/250V	WARNING: Risk of fire. Replace fuse as marked.
\sim	ALTERNATING CURRENT
4	CAUTION: Dangerous Voltage. Refer servicing to qualified personnel.
\Diamond	EQUIPOTENTIALITY
	DANGER: Risk of explosion if used in the presence of flammable anesthetics.
-	FUSE
\longrightarrow	SERIAL COMMUNICATION (1,2) PORTS
<u>~</u>	ANALOG INPUT PORT
<u>~</u>	ANALOG OUTPUT PORT
$\bigcirc\!$	ECG MONITOR INPUT CONNECTION
#	QUANTITY
REF	MODEL NUMBER
2 74 - AB3 ~	DATE OF MANUFACTURE



(€/min)→	CARDIAC OUTPUT CONNECTOR
SN/ 12045675	SERIAL NUMBER
S _⊽ O ₂	OXYGEN SATURATION (%)
	USE WITH BLUE CATHETER CONNECTOR ONLY

Edwards Lifesciences

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Vigilance Monitor Specifications

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B

EQUATIONS FOR CALCULATED PATIENT PARAMETERS

This section describes the equations used to calculate patient parameters displayed on the Cardiac Profile and the Oxygenation Profile screens.

- ▶ NOTE: Calculated patient parameters contain more decimal places of accuracy than are displayed on the screen (e.g., a CO of 2.4 may be a CO of 2.4492). Consequently, attempts to verify the accuracy of the monitor's display using the following equations may produce results that are slightly different from the data computed by the monitor.
- → NOTE: SI Standard International Units

B.1 CARDIAC PROFILE EQUATIONS

1. $CI = CO/BSA \quad (L/min/m^2)$

where: CI - Cardiac Index

CO – Cardiac Output, L/min BSA – Body Surface Area, m²

2. EDV = SV/EF (ml)

where: SV – Stroke Volume, ml

EF - Ejection Fraction, % (efu)

3. EDVI = SVI/EF (ml/m²)

where: SVI – Stroke Volume Index, ml/m²

EF – Ejection Fraction, % (efu)



B.1 CARDIAC PROFILE EQUATIONS (continued)

4. ESV = EDV - SV (ml)

where: EDV - End Diastolic Volume (ml)
SV - Stroke Volume (ml)

5. $ESVI = EDVI - SVI \quad (ml/m^2)$

where: EDVI – End Diastolic Volume Index (ml/m²) SVI – Stroke Volume Index (ml/m²)

6. $SVR = \{(MAP - CVP) \times 80\} / CO$ (dynes-sec/cm⁵) $SVR = \{(MAP_{SI} - CVP_{SI}) \times 60\} / CO$ (kPa-sec/L)

where: SVR - Systemic Vascular Resistance
MAP - Mean Arterial Pressure, mmHg
MAP_{SI} - Mean Arterial Pressure, kPa
CVP - Central Venous Pressure, mmHg
CVP_{SI} - Central Venous Pressure, kPa
CO - Cardiac Output, L/min

7. $SVRI = \{(MAP - CVP) \times 80\} / CI$ (dynes-sec-m²/cm⁵) $SVRI = \{(MAP_{SI} - CVP_{SI}) \times 60\} / CI$ (kPa-sec-m²/L)

where: SVRI — Systemic Vascular Resistance Index MAP — Mean Arterial Pressure, mmHg
MAP_{SI} — Mean Arterial Pressure, kPa
CVP — Central Venous Pressure, mmHg
CVP_{SI} — Central Venous Pressure, kPa
CI — Cardiac Index, L/min/m²

8. $PVR = \{(MPAP - PAWP) \times 80\} / CO$ (dynes-sec/cm⁵) $PVR = \{(MPAP_{SI} - PAWP_{SI}) \times 60\} / CO$ (kPa-sec/L)

where: PVR — Pulmonary Vascular Resistance

MPAP — Mean Pulmonary Artery Pressure, mmHg

MPAP_{SI} — Mean Pulmonary Artery Pressure, kPa

PAWP — Pulmonary Artery Wedge Pressure, mmHg

PAWP_{SI} — Pulmonary Artery Wedge Pressure, kPa

CO — Cardiac Output, L/min

9. $PVRI = \{(MPAP - PAWP) \times 80\} / CI$ (dynes-sec-m²/cm⁵) $PVRI = \{(MPAP_{SI} - PAWP_{SI}) \times 60\} / CI$ (kPa-sec-m²/L)

where: PVRI - Pulmonary Vascular Resistance Index
MPAP - Mean Pulmonary Artery Pressure, mmHg
MPAP_{SI} - Mean Pulmonary Artery Pressure, kPa
PAWP - Pulmonary Artery Wedge Pressure, mmHg

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C

B.1 CARDIAC PROFILE EQUATIONS (continued)

PAWP_{SI} – Pulmonary Artery Wedge Pressure, kPa

CI – Cardiac Index, L/min/m²

10. $SV = (CO/HR) \times 1000$ (mL)

where: SV - Stroke Volume

CO – Cardiac Output, L/min HR – Heart Rate, beats/min

11. SVI = $(CI/HR) \times 1000$ (mL/m^2)

where: SVI - Stroke Volume Index

CI – Cardiac Index, L/min/m² HR – Heart Rate, beats/min

where: LVSWI - Left Ventricle Stroke Work Index

SVI – Stroke Volume Index, mL/m² MAP – Mean Arterial Pressure, mmHg

MAP_{SY} - Mean Arterial Pressure, kPa

PAWP – Pulmonary Artery Wedge Pressure, mmHg PAWP_{SI} – Pulmonary Artery Wedge Pressure, kPa

where: RVSWI – Right Ventricle Stroke Work Index

SVI – Stroke Volume Index, mL/m²

MPAP – Mean Pulmonary Artery Pressure, mmHg MPAP_{SI} – Mean Pulmonary Artery Pressure, kPa CVP – Central Venous Pressure, mmHg CVP_{SI} – Central Venous Pressure, kPa

14. BSA = 71.84 x (WT $^{0.425}$) x (HT $^{0.725}$) /10,000 (m²)

where: BSA — Body Surface Area (DuBois formula)

WT – Patient Weight, kg HT – Patient Height, cm



B.2 OXYGENATION PROFILE EQUATIONS

1. $O_2EI = \{(SaO_2 - SvO_2) / SaO_2\} \times 100$ (%)

where: O₂EI - Oxygen Extraction Index SaO₂ - Arterial O₂ Saturation

SvO₂ - Mixed Venous O₂ Saturation

2. $DO_2 = CaO_2 \times CO \times 10$ (mL O₂/min)

where: DO₂ – Oxygen Delivery

CaO₂ - Arterial Oxygen Content, mL/dL

CO - Cardiac Output, L/min

3. $CaO_2 = (0.0138 \times HGB \times SaO_2) + (0.0031 \times PaO_2)$ (mL/dL)

 $CaO_2 = (0.0138 \times (HGB_{SI} \times 1.611) \times SaO_2)$

 $+ (0.0031 \times (PaO_{2SI} \times 7.5))$ (mL/dL)

where: CaO₂ - Arterial Oxygen Content

HGB - Total Hemoglobin, g/dl

HGB_{SI} – Total Hemoglobin, mmol/L

SaO₂ – Arterial O₂ Saturation

PaO₂ - Partial Pressure of Arterial Oxygen, mmHg

PaO_{2SI} - Partial Pressure of Arterial Oxygen, kPa

4. $CvO_2 = (0.0138 \times HGB \times SvO_2) + (0.0031 \times PvO_2)$ (mL/dL)

 $CvO_2 = (0.0138 \times (HGB_{SI} \times 1.611) \times SvO_2) + (0.0031 \times (PvO_{2SI} \times 7.5))$

(mL/dL)

where: CvO₂ - Venous Oxygen Content

HGB - Total Hemoglobin, g/dl

HGB_{SI} – Total Hemoglobin, mmol/L

SvO₂ – Mixed Venous O₂ Saturation

PvO₂ - Partial Pressure of Venous Oxygen, mmHg

PvO_{25a} Powtal Pressure of Venous Oxygen, kPa

5. $Ca - vO_2 = CaO_2 - CvO_2$ (mL/dL)

where: CaO₂ - Arterial Oxygen Content (mL/dL)

CvO₂ - Venous Oxygen Content (mL/dL)

6. $DO_2I = CaO_2 \times CI \times 10$ (mL $O_2/min/m^2$)

where: DO₂l — Oxygen Delivery Index

CaO₂ – Arterial Oxygen Content, mL/dL

CI – Cardiac Index, L/min/m²

B.2 OXYGENATION PROFILE EQUATIONS (continued)

7.
$$VO_2 = Ca - vO_2 \times CO \times 10$$
 (mL O₂/min)

where: VO₂ - Oxygen Consumption

Ca-vO₂ – Arteriovenous Oxygen Content Difference,

mL/dL

CO – Cardiac Output, L/min

8.
$$VO_2I = Ca-vO_2 \times CI \times 10$$
 (mL O₂/min/m²)

where: VO₂I - Oxygen Consumption Index

Ca-vO₂ – Arteriovenous Oxygen Content Difference,

mL/dL

CI – Cardiac Index, L/min/m²

9.
$$O_2ER = (Ca - vO_2 / CaO_2) \times 100$$
 (%)

where: O₂ER - Oxygen Extraction Ratio

CaO₂ – Arterial Oxygen Content, mL/dL

Ca-vO₂ – Arteriovenous Oxygen Content Difference, mL/dL

10. VQI =
$$\frac{\{1.38 \times HGB \times (1.0 - (SaO_2/100)) + (0.0031 \times PAO_2)\}}{\{1.38 \times HGB \times (1.0 - (SvO_2/100)) + (0.0031 \times PAO_2)\}} \times 100$$
 (%)

$$VQI = \frac{\{1.38 \times HGB_{SI} \times 1.611344 \times (1.0 - (SaO_2/100)) + (0.0031 \times PAO_2)\}}{\{1.38 \times HGB_{SI} \times 1.611344 \times (1.0 - (SvO_2/100)) + (0.0031 \times PAO_2)\}} \times 100 \text{ (\%)}$$

where: VQI - Ventilation Perfusion Index

HGB - Total Hemoglobin, g/dL

HGB_{SI} – Total Hemoglobin, mmol/L

 SaO_2 – Mixed Arterial O_2 Saturation SvO_2 – Mixed Venous O_2 Saturation

 PAO_2 – Alveolar O_2 Tension

and:

$$PAO_2 = ((PBAR - PH_20) \times FiO_2) - PaCO_2 \times (FiO_2 + (1.0 - FiO_2)/0.8)$$

where: FiO₂ – Fraction of Inspired Oxygen PBAR – 760 mmHg

PBAR - 760 mmHg $PH_2O - 47 \text{ mmHg}$ $PaCO_2 - 40 \text{ mmHg}$

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C

VIGILANCE MONITOR DEFAULT SETTINGS

The information in this section defines the factory default settings for the *Vigilance* Monitor that includes: Alarm Limits, Display Settings, Patient Data Screen Defaults, and Communication Port Settings. Also included in this section is information about supported digital devices.

C.1 ALARM LIMITS

<u>Parameter</u>	<u>High Limit</u>	Low Limit	<u>Status</u>	<u>Units</u>
CCO	14.0	2.0	On	L/min
SvO_2	99.0	10.0	On	%
CCI	7.0	1.0	On	L/min/m ²
EDV	300	100	On	ml
EDVI	150	70	On	ml/m ²

C.2 DISPLAY SETTINGS

Trend Time Scale	2 hours
Graph 1	SvO_2 (scale 0–100)
Graph 2	CCO (scale 0–12)
Graph 3	EDV (scale 50-250)
Language	English
Temperature Units	°C
International Units	No
Time Format	Military (24-hour)
CO/CCO	Not indexed to body surface area
SVR	Not indexed to body surface area
EDV/ESV	Not indexed to body surface area
SV	Not indexed to body surface area



C.3 PARAMETER GROUP SELECTION

Group 1 BT HR
EF SV
EDVI ESV
CCI SVR

C.4 PATIENT DATA SCREEN DEFAULTS

 $PvO_2 = 40 \text{ mmHg}$ $PaO_2 = 100 \text{ mmHg}$

C.5 COMMUNICATION PORT SETTINGS

	Parameter Device
Analog Input Ports (1, 2, 3, 4)	None
Analog Output Ports (1, 2)	None
Digital Port COM 1	None
Digital Port — COM 2	None

C.6 SUPPORTED DIGITAL DEVICES

- Patient Monitors that use the *Vigilance* Standard Communication Protocol (IFMout). For more information on this communication protocol, contact Edwards Technical Support (see Appendix F).
- SpaceLabs Medical Patient Care Management Systems (PCMS™) that use the SpaceLabs Universal Flexport* Communications Protocol (Flexport*).
- Please contact Edwards Technical support at 1.800.822.9837 or 949.250.2222 for a complete listing of supported digital devices, such as printers.

D

COMPUTATION CONSTANTS

The computation constants listed in the following tables are used by the *Vigilance* Monitor in the BOLUS CO mode to compute cardiac output employing either a bath probe setup or in-line temperature probe. The *Vigilance* Monitor automatically senses the type of injectate temperature probe being used, and the corresponding injectate temperature, catheter size and injectate volume define the computation constant. When a bath temperature probe is used, the computation constant is determined before sensing an injection. When an in-line temperature probe is used, the computation constant is determined after sensing an injection.

→ NOTE: The computation constants given below (Tables D-1 and D-2) are nominal and generally applicable to the specified catheter sizes. For computation constants specific to the catheter being used, refer to the catheter package insert. Model specific computation constants can be manually entered in the BOLUS CO mode after pressing the BOLUS SETUP key.

Table D-1. Computation Constants for use with a Bath Temperature Probe

Injectate Temperature Range*	Injectate	Catheter Size, French				
	Volume	8	7.5	7	6	5.5
Room Temp.	10	0.612	0.594	0.595	0.607	0.616
22.5–27°C	5	0.301	0.283	0.287	0.304	0.304
	3	0.177	0.159	0.165	0.180	0.180
Room Temp.	10	0.588	0.582	0.578	0.597	0.606
18-22.5°C	5	0.283	0.277	0.274	0.297	0.298
	3	0.158	0.156	0.154	0.174	0.175
Cold (Iced)	10	0.563	0.575	0.562	0.573	0.581
5-18°C	5	0.267	0.267	0.262	0.278	0.281
	3	0.148	0.150	0.144	0.159	0.161
Cold (Iced)	10	0.564	0.564	0.542	0.547	0.555
0–5°C	5	0.262	0.257	0.247	0.259	0.264
	3	0.139	0.143	0.132	0.144	0.148

NOTE: Refer to catheter package insert for catheter specific computation constant values.

Table D-2. Computation Constants for use with an In-Line Temperature Probe

Injectate Temperature Range*	Injectate Volume	Catheter Size, French				
		8	7.5	7	6	5.5
Room Temp.	10	0.601	0.599	0.616	0.616	0.624
22.5–27°C	5	0.294	0.301	0.311	0.307	0.310
Room Temp.	10	0.593	0.593	0.603	0.602	0.612
18-22.5°C	5	0.288	0.297	0.295	0.298	0.304
Cold (Iced)	10	0.578	0.578	0.570	0.568	0.581
5-18°C	5	0.272	0.286	0.257	0.276	0.288
Cold (Iced)	10	0.562	0.563	0.537	0.533	0.549
0–5°C	5	0.267	0.276	0.217	0.253	0.272

^{*} To optimize cardiac output measurement, it is recommended that the temperature of the injectate corresponds to one of the temperature ranges listed in the catheter package insert.

NOTE: Refer to catheter package insert for catheter specific computation constant values.

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APPENDIX

E

PERFORMANCE CHECK

E.1 Introduction

This section provides a performance test of the operation of the *Vigilance* Continuous Cardiac Output Monitor. This procedure is designed to be followed in the order it is presented here. Perform these tests in the order presented to assure the user that the monitor is functioning properly. If the monitor does not perform these tests as specified, please contact Technical Support at 1.800.822.9837 or 949.250.2222.

E.2 Equipment Required

This procedure requires the following items:

Item:	Model Number	Description
	OM2	Optics Module
	9511A	Field Tester
	744HF75	Oximetry catheter (unopened)
	or	•
	746HF8	Oximetry catheter (unopened)
	70CC2	Catheter Interface Cable

E.3 Power On Self Test (POST)

Perform the following steps for the Power On Self Test.

- 1. Place the Vigilance monitor on a table.
- 2. Check for loose hardware by tilting the unit to the left side, the right side, to the back, and to the front.
- 3. Connect the monitor to an appropriate AC power source.
- 4. Turn the monitor ON by pressing the power switch.
- **5.** If any power up system fault messages appear, carefully record the exact message and call Technical Support at 1.800.822.9837 or 949.250.2222.

E.4 System Setup for Performance Check

1. If the patient data is less than 24 hours old, the trend screen will then appear with the following message:

Clear patient data profiles?

Press YES.

- Press SETUP.
- 3. Make sure both CO/CCO and SVR display non-indexed values. If they are set for indexed values, move the cursor to that field and press change so non-indexed is displayed.
- Press SYSTEM CONFIG.
- 5. Select Analog Input from the touch bar.
- **6.** Press **CURSOR** until Parameter is backlit. Press change until -None- appears.
- 7. Press **PORT2**. Repeat steps 5 and 6 to set all four analog ports to -None-.
- 8. Press HOME.
- Connect the OM2 to the monitor.
- 10. Connect the catheter optical connector to the OM2.
- 11. Select SvO₂ from the touch bar.
- **12.** Select In Vivo Calibration. A warning will be displayed because the catheter is still in the package and not in a patient. Select Continue from the touch bar.
- 13. Select Draw from the touch bar.
- 14. Enter the following values:

SvO₂: 70.0 HGB: 11.5 Hct: 35

- 15. Press CAL
- **16.** After the Optical Module Update is complete, the screen should revert to the Home screen, and SvO₂ should begin to trend at 70.

E.5 Bolus CO Performance Check

→ NOTE: Make sure an injectate Temperature probe is not connected to the cable.

- 1. Connect the 70CC2 cable to the Catheter Cable Connector on the front panel.
- 2. Connect the 9511A Field Tester to the white thermistor connector on the end of the 70CC2.
- 3. Select Bolus CO from the touch bar.
- 4. Select Bolus Setup. Computation Constant should read Yes. Press RETURN.
- 5. Select Comp Const.
- Using the touch bar at the bottom of the screen, enter 0247. The computation constant should be displayed as 0.247. Press RETURN.
- 7. Press **START BOLUS** if in the manual mode, or just continue if in the automatic mode. Press and hold the red button on the 9511A field tester for 10 seconds. The cardiac output should be between 6.5 and 7.9 liters per minute (lpm).
- 8. Repeat step 6 to obtain a total of three cardiac output values.
- 9. Press EDIT BOLUS. If any curves are outside the specified range, touch the touch bar just below the value to delete it from the calculation. Press RESUME SERIES to obtain a total of at least three good cardiac output values.
- **10.** From the Edit Bolus screen, press **PATIENT DATA**.

E.6 Cardiac Profile Performance Check

1. Press HT/WT/BSA key to go into Patient Information screen. Enter the following values:

Height: 72 inches Weight: 160 pounds

- 2. Press RETURN.
- 3. Press EDIT.

13 XF 3

4. Enter the following values:

MAP: 85 mmHg CVP: 8 mmHg MPAP: 24 mmHg PAWP: 14 mmHg HR: 60 bpm

- 5. Press CALC.
- 6. The calculated values should be within the following ranges:

CO: CI: 3.3 - 4.06.5 - 7.91513 - 1839 SVR: 780 - 948SVRI: PVR: 101 - 123 PVRI: 196 - 239 RVSWI: 12 - 14 LVSWI: 53 - 65 SV: 108 - 132 SVI: 55 - 67

E.7 Oxygen Profile Performance Check

- 1. Press OXYGEN PROFILE.
- 2. Press EDIT.
- **3.** Enter the following values:

81 % SaO₂: SvO₂: 70 % g/dL HGB: 11.5 37 PvO₂: mmHg PaO₂: 95 mmHg 1.00 FiO₂:

- 4. Press CALC.
- 5. The calculated values should be within the following ranges:

VO₂: 115 - 152 VO₂I: 59 - 78 DO₂: 855 - 1039 DO₂I: 441 - 535 CO: 6.5 - 7.9 CI: 3.3 - 4.0 VQI: 75%

F SERVICE AND SUPPORT

- ❖ WARNING: THE VIGILANCE MONITOR CONTAINS NO USER-SERVICEABLE PARTS. REMOVAL OF THE COVER OR DISASSEMBLY WILL EXPOSE HAZARDOUS VOLTAGES. TO AVOID INJURY OR INSTRUMENT DAMAGE, DO NOT DISASSEMBLE OR SERVICE THE INSTRUMENT. REFER SERVICING TO THE MANUFACTURER.
- ❖ WARNING: FOR PROTECTION AGAINST FIRE, REPLACE THE FUSE WITH ONE OF THE SAME TYPE AND RATING.

F.1 Service and Support

 The Vigilance Monitor does not need routine servicing to maintain its optimum performance level. See Section 4, "Troubleshooting Guide," of this manual for potential difficulties, causes of those difficulties, and suggested solutions.

Edwards provides a technical services support department for user support. Telephone inquiries for service, technical support, supplies, or miscellaneous questions are made by calling Edwards Technical Support at the telephone numbers listed below.

To respond to questions, this department will need the serial number of the unit and, if possible, the version of software. The serial number is found on the back panel of the *Vigilance* Monitor. Press the following keys in sequence to display the software version: **SETUP**, **SYSTEM CONFIG**.

• Monitor Problem Troubleshooting, call Edwards Technical Support:

Inside the U.S. and Canada (24 hours): 1.800.822.9837 Outside the U.S. and Canada (24 hours): 949.250.2222

 Return address for repair of electronic items (in the U.S.) - Please contact Edwards Technical Support prior to returning any electronic equipment:

Edwards Lifesciences LLC 1402 Alton Parkway Irvine, CA 92614

Attention: Service Operations	
RGA#	

- Sales and nontechnical questions should be directed to the Customer Service Department at 1.800.4.A-HEART (1.800.424.3278) or 949.250.2500.
- Return address for the evaluation of non-electronic items (e.g. catheters) - Please contact Edwards Customer Service prior to returning any non-electronic items:

Edwards Lifesciences LLC 1402 Alton Parkway Irvine, CA 92606

Attention:	Returned Goods	
RGA#		

G

WARRANTY

Edwards Lifesciences (Edwards) warrants that the *Vigilance* monitor is fit for the purposes and indications described in the labeling for a period of one (1) year after the date of purchase when used in accordance with the directions for use. Unless the equipment is used in accordance with such instructions, this warranty is void and of no effect. No other express or implied warranty exists, including any warranty of merchantability or fitness for a particular purpose. This warranty does not include cables, probes, or batteries used with this *Vigilance* monitor. Edwards' sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the *Vigilance* monitor at Edwards' option. Edwards shall not be liable for proximate, incidental, or consequential damages.

Edwards shall not be obligated under this warranty to repair or replace a damaged or malfunctioning *Vigilance* monitor if such damage or malfunction is caused by the customer's use of catheters other than those manufactured by Edwards.

Warranty

GLOSSARY

ALARMS

Audible and visual indicators that notify operator that a measured patient parameter is outside the alarm limits.

ALARM LIMITS

Maximum and minimum values for monitored patient parameters.

ARTERIAL OXYGEN CONTENT (CaO₂)

The amount of oxygen carried in the arterial blood, both in the dissolved state and the amount bound to hemoglobin. Content of oxygen (CO₂) can be expressed as milliliters of oxygen per deciliter (mL/dL) of blood or as volume percent (vol %).

ARTERIAL OXYGEN SATURATION (SaO₂)

Percentage of hemoglobin saturated with oxygen in the arterial blood.

ARTERIOVENOUS OXYGEN CONTENT DIFFERENCE (Ca-vO₂)

The difference between the content of oxygen in the arterial and venous side. This difference is expressed as milliliters of oxygen per deciliter (mL/dL) of blood or as volume percent (vol %).

BASELINE BLOOD TEMPERATURE

Blood temperature that serves as the basis for cardiac output measurements.

BLOOD TEMPERATURE (BT)

Temperature of the blood in the pulmonary artery when the catheter is properly positioned.

BODY SURFACE AREA (BSA)

Surface area of a patient's skin.

BOLUS CO MODE

Functional state of the *Vigilance* Monitor in which cardiac output is measured by the bolus thermodilution method.

BOLUS INJECTION

A known volume of iced or room temperature fluid, which is injected into a port on the pulmonary artery catheter and serves as the indicator for measuring cardiac output.

CARDIAC INDEX (CI)

Cardiac output adjusted for body size.

CARDIAC OUTPUT (CO)

Volume of blood ejected per minute from the heart into systemic circulation.

CENTRAL VENOUS PRESSURE (CVP)

Mean pressure in the superior vena cava (right atrium). Indicates venous return to the right side of the heart.

COMPUTATION CONSTANT

A constant used in the cardiac output equation that accounts for density of blood and injectate, injectate volume, and indicator loss in the catheter.

CONTINUOUS MODE

Functional state of the *Vigilance* Monitor in which cardiac output is trended on a continuous basis.

CURSOR

Highlighted portion of monitor screen used to indicate choices of variables which can be entered.

DEFAULT SETTINGS

Initial operating conditions assumed by the monitor.

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Glossary -1

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DRUG CALCULATION

The *Vigilance* system calculates the desired values based on data entered by the user

EJECTION FRACTION (EF)

Percentage of blood volume ejected from the right heart during systole.

END DIASTOLIC VOLUME (EDV)

Volume of blood in right ventricle at end diastole.

END DIASTOLIC VOLUME INDEX (EDVI)

Right heart end diastolic volume adjusted for body size.

END SYSTOLIC VOLUME (ESV)

Volume of blood in right heart at end systole.

END SYSTOLIC VOLUME INDEX (ESVI)

Right heart end systolic volume adjusted for body size.

EVENT

An episode during monitoring that the operator wishes to mark on the trend graph.

FRACTION OF INSPIRED OXYGEN (FiO₂)

The fraction of oxygen in the inspired air.

HEART RATE (HR)

Number of ventricular contractions per minute.

HEMOGLOBIN (HGB)

Oxygen carrying component of red blood cells.

ICON 🔉

The "No Alarms" icon appears on all screens when alarms are suspended.

INIECTATE

Glossary-2

Fluid used for bolus thermodilution cardiac output measurement.

INJECTATE TEMPERATURE (IT)

Measured temperature of the injectate used for bolus thermodilution cardiac output measurement.

INTELLICATH CATHETER

Edwards thermodilution pulmonary artery catheter used to measure cardiac output continuously.

LEFT VENTRICULAR STROKE WORK INDEX (LVSWI)

A measure of the amount of work the left ventricle exerts during systole, adjusted for body size.

MEAN ARTERIAL PRESSURE (MAP)

Average systemic arterial blood pressure.

MEAN PULMONARY ARTERY PRESSURE (MPAP)

Average blood pressure measured in the pulmonary artery.

·MIXED VENOUS OXYGEN SATURATION

Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the pulmonary artery.

OXIMETRY (SvO₂)

Percentage of hemoglobin saturated with oxygen in the blood.

OXYGEN DELIVERY (DO₂)

Amount of oxygen in milliliters per minute (ml/min) delivered to the tissues.

OXYGEN DELIVERY INDEX (DO₂I)

Amount of oxygen in milliliters per minute (ml/min) delivered to the tissues, adjusted for body size.

OXYGEN CONSUMPTION (VO₂)

Amount of oxygen in milliliters per minute (ml/min) used by the tissues.

OXYGEN CONSUMPTION INDEX (VO₂I)

Amount of oxygen in milliliters per minute (ml/min) used by the tissues, adjusted for body size.

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OXYGEN EXTRACTION INDEX (O2EI)

 O_2EI is determined by using dual oximetry, SaO_2 and SvO_2 and evaluates the ratio of oxygen extracted to the amount of oxygen supplied.

OXYGEN EXTRACTION RATIO (O₂ER)

O₂ER is the ratio of oxygen content difference to the amount of oxygen supplied.

PULMONARY ARTERY WEDGE PRESSURE (PAWP)

Pressure obtained from the pulmonary artery catheter when balloon is inflated and catheter tip progresses into a more distal branch of the pulmonary artery. Reflects left atrial pressure when there is no mechanical obstruction (e.g. left atrial tumors, or pulmonary vein obstruction) between the balloon tip and the left atrium.

PULMONARY VASCULAR RESISTANCE (PVR)

A derived measure of impedance to blood flow from right ventricle (afterload).

PULMONARY VASCULAR RESISTANCE INDEX (PVRI)

Pulmonary vascular resistance adjusted for body size.

RIGHT VENTRICULAR STROKE WORK INDEX (RVSWI)

A measure of the amount of work the right ventricle exerts during systole, adjusted for body size.

SIGNAL

Induced temperature change which is used to measure cardiac output.

STAT MODE

Presents fast trend estimates of CCO/CCI, EDV/EDVI values.

STROKE VOLUME (SV)

Amount of blood ejected from the ventricles with each contraction.

STROKE VOLUME INDEX (SVI)

Stroke volume adjusted for body size.

SYSTEMIC VASCULAR RESISTANCE (SVR)

A derived measure of impedance to blood flow from left ventricle (afterload).

SYSTEMIC VASCULAR RESISTANCE INDEX (SVRI)

Systemic vascular resistance adjusted for body size.

THERMAL FILAMENT

Area on the CCO thermodilution catheter that transfers small amounts of energy into the blood to serve as indicator for trending cardiac output continuously.

THERMISTOR

Temperature sensor near the tip of the pulmonary artery catheter.

THERMODILUTION

A variant of the indicator dilution technique using temperature change as the indicator.

TREND

A collection of historical data points.

VENOUS OXYGEN CONTENT (CvO₂)

The amount of oxygen carried in the venous blood, both in the dissolved state and the amount bound to hemoglobin. Content of oxygen (CO₂) can be expressed as milliliters of oxygen per deciliter (mL/dL) of blood or as volume percent (vol %).

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Glossary -3

VENOUS OXYGEN SATURATION

Percentage of hemoglobin saturated with oxygen in the venous blood.

VENTILATION PERFUSION INDEX (VQI)

VQI is determined by using dual oximetry, SaO₂ and SvO₂. This value is a derivation of the intrapulmonary shunt equation and provides an estimate of intrapulmonary shunt value.

WASHOUT CURVE

Indicator dilution curve produced by a bolus injection. Cardiac output is inversely related to the area under this curve.

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Reader Comment Form

Edwards Lifesciences welcomes your comments on the organization, content, and format of this manual. Does this manual serve your needs? If not, how can we improve it? After you have read this manual and have had the opportunity to use the Edwards *Vigilance* Monitor, please take a few moments and let us know your comments. This is the best way that we know to improve our products.

Organization	Yes	No				
Is the material within this manual well organized for your needs?						
Did the descriptions and procedures follow a logical sequence?						
Were you able to find an item easily by using the Table of Contents or the Index?						
Content						
Is the material described in this manual easy to follow and understandable?						
Do the appendices provide useful reference information?						
Does this manual provide all the information you need?						
Format						
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Vigilance Monitor Operator's Manual February 2004

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Metracor RODA Monitoring System Labeling

At the time of this 510(k) submission, labeling is unavailable for the Metracor RODA Monitoring System.

Instead of labeling, a copy of the 510(k) Summary and Indications for Use Statement for the RODA Monitoring System (K011238) are included here.

10(k) Document Mail Center (HFZ-401)

January 3, 2002

Page 4

KOII238

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Attachment 1: 510(k) Summary

510(k) Summary

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Submitter:

Metracor Technologies, Inc. 11425 Sorrento Valley Road San Diego, CA 921221 Tel: (619) 793-3300

Fax: (619) 793-3315

Contact Person: George McHugh, Vice President, Operations

Date Prepared:

January 3, 2002

Name of Device and Name/Address of Sponsor

Device Name:

RODA® Monitoring System

Sponsor:

Metracor Technologies, Inc. 11425 Sorrento Valley Road San Diego, CA 921221

Common or Usual Name

RODA®

Classification Name

INFUSION PUMP, ANALYTICAL SAMPLING--21 C.F.R. § 880.5725

0 12:

10(k) Document Mail Center (HFZ-401) January 3, 2002 Page 5

PREPROGRAMMED DIAGNOSTIC COMPUTER-- 21 C.F.R. § 870.1435

INDWELLING BLOOD CARBON DIOXIDE ANALYZER--21 C.F.R. § 868.1150

INDWELLING BLOOD OXYGEN PARTIAL PRESSURE ANALYZER--21 C.F.R. § 868.1200

Predicate Devices

- Metracor Technologies, Inc. VIA 1-01 Infusion Pump/Blood Chemistry System (K935778)
- 2. Baxter Healthcare Corporation Model COM-3 (K896930)
- 3. Cardiodynamics International Corporation BioZ System (K963183)
- 4. Pulsion Continuous Pulse Contour Cardiac Output Monitor (K001762)
- 5. Lidco, Ltd. PulseCO Hemodynamic Monitor CM71 (K010049)
- 6. Sorba Medical Systems, Inc. Model CIC-1000 (K895017)
- 7. Renaissance Technology, Inc. IQ System (K981720)
- 8. Pulse Metric Dyna Pulse Pathway (no 510(k))

Intended Use

The RODA® Monitoring System (RODA®) is an integrated medical device intended for the real-time, on-line monitoring and trending of hemodynamic parameters (including cardiac output), arterial blood gases, hemoglobin and blood chemistry, when used in conjunction with a preexisting radial arterial line.

Technological Characteristics

RODA® operates by utilizing a peristaltic pump connected to an arterial catheter to withdraw a small amount of blood, which then comes in contact with an in-line electrochemical sensor set. An array of sensors analyzes the sample for arterial blood gases, electrolytes, glucose, and hematocrit, and the measured and/or derived values are displayed on a monitor after approximately 1 minute. The pump and sensors operate in a closed system; thus, when analysis is completed, the blood is returned to the patient. The values produced by analysis of the arterial blood are applied to standard equations to display oxyhemoglobin saturation and oxygen content.

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Automated sampling can be performed at preset intervals or manually (with a minimum interval of 10 minutes). RODA® can also be connected to a temperature probe (not supplied with RODA®) to provide a body temperature measurement to increase the accuracy of calculated oxyhemoglobin saturation.

When used for hemodynamic monitoring, the amplified signal from a pressure transducer (not supplied with RODA®) connected to the radial artery catheter provides the source for measured systolic, diastolic, and mean blood pressures, and heart rate. The pressure signal is also used by the system to monitor and trend cardiac output, which is determined by an algorithm that converts arterial pressure into aortic flow. RODA® displays measured and derived hemodynamic parameters on a beat-to-beat basis and automatically displays and trends oxygen delivery, the product of the cardiac output and arterial oxygen content, calculated from parameters determined from the most recent blood withdrawal.

Summary Basis for the Finding of Substantial Equivalence

RODA® has the same intended use and indications for use as the predicate devices. All of the predicates, like RODA®, are indicated for use in monitoring hemodynamic and/or blood chemistry parameters. In addition, the parameters measured by RODA® are identical to the parameters measured by the predicates. Most of the technological features of RODA® are substantially equivalent to the predicate VIA LVM System. The RODA® System also has the ability to monitor cardiac output. Predicate devices such as the Baxter COM-3 and the Pulsion and PulseCO Monitors also perform this function. Like predicate devices, the RODA® System derives cardiac output by mathematical analysis of an arterial blood pressure signal. In clinical testing, the algorithm used in RODA® has been validated for use to monitor stroke volume (SV), and therefore cardiac output, without calibration to thermodilution in patients aged 20-78 with stroke volumes ranging from 29.9-141.2 ml with acceptable accuracy and reproducibility. The range of cardiac output values as determined by thermodilution observed in the clinical testing was 2.0-9.3 L/min.1/

Thus, RODA® is substantially equivalent to a combination of the predicate devices cited.

 $[\]underline{I}/$ Jansen JRC et al. A comparison of cardiac output derived from the arterial pressure wave against thermodilution in cardiac surgery patients. Br. J. Anaesthesia. 87(2): 212-22 (2001).

510(k) Number (if known): KO11238					
Device Name: RODA® (Real Time Oxygen Dynamics Analysis) Monitoring System					
Indications For Use:					
The RODAS Monitoring System is indicated for the real-time, on-line monitoring and trending of hemodynamic parameters, arterial blood gases, hemoglobin and blood chemistry when used in conjunction with a preexisting radial artery line. The device is specifically indicated for use to monitor cardiac output and trends in cardiac output.					
The parameters measured by the system are listed below Arterial blood gases Oxygen partial pressure (PaO2) Carbon dioxide partial pressure (PaCO2) pH Electrolytes Nat, K*, Ca++ Hematocrit (Het) Glucose Arterial blood pressure Systolic Diastolic Mean Heart rate (HR) Body temperature (T) Parameters calculated or derived by the system Stroke volume (SV) Stroke volume index (SVI) Cardiac output (CO) Cardiac index (CI) Systemic vascular resistance (SVR) Systemic vascular resistance index (SVRI) Hemoglobin concentration (Hb) Arterial oxybemoglobin saturation (SaO2) Arterial oxygen content (CaO2) Alveolar-arterial oxygen partial pressure gradient (A-a gradient) Oxygen delivery (DO2) Total carbon dioxide (TCO2) Bicarbonate concentration (HCO3] Base deficit (BD) Partial pressure of alveolar oxygen (PAO2) PaO2/FiO2 ratio (PF) PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) Division of Cardiovascular a Respiratory Devices 510(k) Number (AD12) Division of Cardiovascular a Respiratory Devices 510(k) Number (AD12)					
Prescription Use OR Over-The-Counter Use					

NNDC - 86255/1 -#1402947 v1

DPT Shipping Container Labeling

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REF: PX600P

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STERILE TRUWAVE OPT PX -- 600

Qty # : **1**

STERILE

(2) For single use only

Attention, 300 instructions for use

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is opened or damaged

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Lot No

LOT

Use By

Manufactured by an affiliate of: Edwards Lifesciences LLC Irvine, CA 92614 – 5686 USA Made in Dominican Republic

EU EU representative Edwards Lifesciences Germany GmbH 85716 Unterschleissheim



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DPT Unit Labeling

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🖟 Edwards Lifesciences

REF: PX(600)

Qty::1

TruWave Disposable Pressure Transducer with Stopcock

For single use only

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Contents of package sterile and field path not pyrogenic I) enopened and undamaged.

Ex only

See package insert for detailed information.

Do not useff package is opened or damaged.

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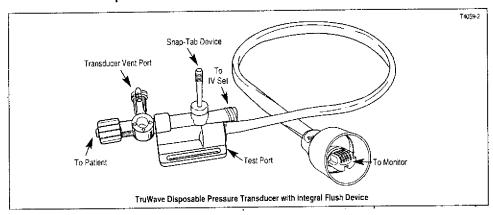
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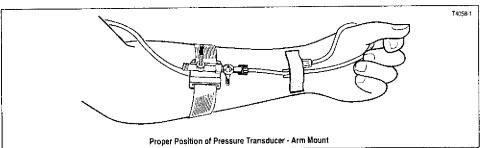
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DPT Directions for Use

Edwards Lifesciences

Pressure Monitoring Kit with TruWave Disposable Pressure Transducer





For single use only

These are general instructions for setting up a pressure monitoring system with the TruWave disposable pressure transducer. Since kit configurations and procedures vary according to hospital preferences, it is the responsibility of the hospital to determine exact policies and procedures.

Caution: The use of lipids with the TruWave disposable pressure transducer may compromise product integrity.

Edwards Lifesciences, Edwards, Snap-Tab and TruWave are trademarks of Edwards Lifesciences Corporation; TruWave is registered in the U.S. Patent and Trademark Office.

Concept/Description

The Edwards Lifesciences pressure monitoring kit with the TruWave disposable pressure transducer (model series PX) is a sterile, single-use kit that monitors pressures when attached to pressure monitoring catheters. The disposable sterile cable (available in 12-inch/30 cm and 48-inch/120 cm lengths) interfaces exclusively with an Edwards cable that is specifically wired for the monitor being used.

The TruWave disposable pressure transducer has a straight, flowthrough design across the pressure sensor, and is available with or without the integral flush device.

 $_{i_{\alpha\beta}}$ 0 130

Indications

The pressure monitoring kit with TruWave disposable pressure transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.

Contraindications

There are no absolute contraindications for using the TruWave disposable pressure transducer in patients requiring invasive pressure monitoring.

Flush devices should not be used when monitoring intracranial pressures.

Procedure

- Ensure that the cable is compatible with the monitor being used.
 Connect the reusable cable to the monitor, and turn the monitor on to allow the electronics to warm up.
- Using aseptic technique, remove the transducer and kit from the sterile packaging.
- Add additional components as needed to complete the monitoring system per hospital policy.
- 4. Ensure that all connections are secure
- 5. Connect the transducer cable to the reusable cable
- Remove all air from the heparinized IV flush solution bag per hospital policy.

Caution: If all air is not removed from the bag, air may be forced into the patient's vascular system when the solution is exhausted.

- Close the roller clamp on the IV set and connect the IV set to the IV flush bag. Hang the bag approximately 2 feet (60 cm) above the patient. This height will provide approximately 45 mmHg of pressure to prime the setup.
- 8. Fill the drip chamber halfway with flush solution by squeezing the drip chamber. Open the roller clamp.
- 9. To fill system
 - For transducers without integral flush device (Snap-Tap device), fill system per hospital policy.
 - For transducers with integral flush device, flow is provided by pulling on the Snap-Tab device and discontinued by releasing the Snap-Tab device.
- 10. For kits with IV sets attached, open the transducer vent port by turning the stopcock handle. Deliver flush solution first through the transducer and out through the vent port, then through the remaining kit by turning the appropriate stopcocks. Remove all air bubbles.

Caution: Significant distortion of the pressure waveform or air emboli can result from air bubbles in the setup.

- Replace all vented caps on sideports of the stopcocks with nonvented caps.
- Mount the transducer either on the patient's body per hospital
 procedure or on an IV pole using the appropriate clamp and holder. If
 holder is used, snap transducer into place.

13. Pressurize the IV flush solution bag. Flow rate will vary with pressure across the flush device. The flow rates with the IV bag pressurized to 300 mmHg are as follows:

3±1 ml/hr (DPT with blue Snap-Tab device)

30±10 ml/hr (DPT with yellow Snap-Tab device).

- Connect pressure lubing to the catheler per manufacturer's instructions.
- 15. Flush system per hospital policy.

Caution: After each fast-flush operation, observe the drip chamber to verify that the continuous flush rate is as desired (see Complications).

Zeroing and Calibration

- Adjust the level of the transducer vent port (the fluid-air interface) to correspond to the chamber where pressure is being measured. For example, in cardiac monitoring, zero at level of the right atrium. This is at the phiebostatic axis, determined by the intersection of the midaxillary line and the fourth intercostal space.
- 2. Remove the non-vented cap and open the vent port to the atmosphere.
- 3. Adjust the monitor to read zero mmHg
- Check monitor calibration using procedure recommended by the monitor manufacturer.
- Use the Model 59-UCAL Pressure Transducer Simulator/Tester in conjunction with the Model PXSIM (TruWave Pressure Transducer Simulator/Tester tubing set) to verify pressure readings without compromising sterificy of the system (Figure 1).

Instructions are included with the TruWave Pressure Transducer Simulator/Tester tubing set.

- 6. Close the vent port to the atmosphere and replace the nonvented cap.
- 7. System is ready to begin monitoring pressure.

Testing Dynamic Response

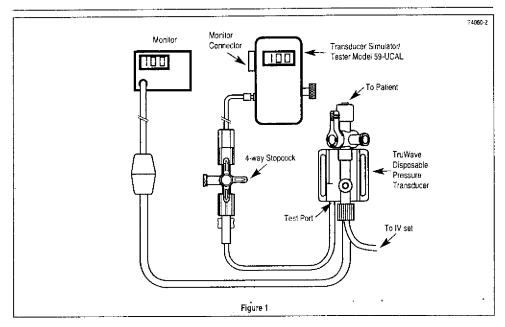
The assembly may be lested for dynamic response by observing the pressure waveform on an oscilloscope or monitor. Bedside determination of the dynamic response of the catheter, monitor, kit, and transducer system is done after the system is flushed, attached to the patient, zeroed, and calibrated. A square-wave test may be performed by pulling the Snap-Tab device and releasing quickly.

Note: Poor dynamic response can be caused by air bubbles, ctotting, excessive lengths of tubing, excessively compliant pressure tubing, small bore tubing, loose connections, or leaks.

Routine Maintenance

Follow hospital policies and procedures for frequency of zeroing the transducer and monitor and for replacing and maintaining pressure monitoring lines. The TruWave disposable pressure transducer is precalibrated and has a negligible drift with time (see Specifications).

 Adjust zero pressure reference each time level of the patient is changed.



Caution: When rechecking zero or verifying accuracy, ensure that the non-vented cap is removed before opening the transducer vent port to the atmosphere.

- Periodically check fluid path for air bubbles. Ensure that connecting lines and stopcocks remain lightly fitted.
- Periodically observe the drip chamber to verify that the continuous flush rate is as desired.
- The Centers for Disease Control recommends replacing disposable or reusable transducers at 96-hour intervals. Relace other components of the system, including the tubing, continuous-flush device, and flush solution, at the time the transducer is replaced.

Warnings

- Do not use the flush device during intracranial pressure monitoring.
- For severely fluid-restricted patients such as neonates and children, use an infusion pump in series with the flush device to accurately regulate the minimum amount of flush solution needed to maintain catheter patency while allowing continuous pressure monitoring. High pressures, which may be generated by an infusion pump at certain flow rates, may override the flush device restriction, resulting in fast flushing at the rate set by the pump.
- Do not allow air bubbles to enter the setup, especially when monitoring atrial pressures.

- Avoid contact with any topical cream or ointment that attacks polymeric materials.
- Do not expose electrical connections to fluid contact.
- Do not autoclave the reusable cable.

Complications

Sepsis/Infection

Positive cultures can result from contamination of the pressure setup. Increased risks of septicemia and bacteremia have been associated with blood sampling, infusing fluids, and catheter related thrombosis (Refs. 1, 2 & 7).

Air Emboli

Air can enter the patient through stopcocks that are inadvertently left open, from accidental disconnection of the pressure setup, or from flushing residual air bubbles into the patient (Ref. 6).

Clotted Catheter and Bleed-Back

If the flush system is not adequately pressurized relative to the patient's blood pressure, blood bleed-back and catheter clotting may occur.

Overintusion

Excessive flow rates may result from pressures greater than 300 mmHg. This may result in a potentially harmful increase in blood pressure and fluid overdose (Ref. 3).

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Abnormal Pressure Readings

Pressure readings can change quickly and dramatically because of loss of proper calibration, loose connection, or air in the system (Refs. 3 & 6).

Warning: Abnormal pressure readings should correlate with the patient's clinical manifestations. Verify transducer function with a known amount of pressure before instituting therapy.

How Supplied

TrutWave disposable pressure transducers are supplied sterile in preconnected monitoring kits (either standard design or special order). Contents sterile and nonpyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Do not resterilize.

Technical Assistance

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Prices, specifications, and model availability are subject to change without notice.

This product is manufactured and sold under one or more of the following US patent(s): US Patent No. 4,576,181; 4,610,256; RE33,518; 5,564,951; 5,803,770; and corresponding foreign patents. Likewise, additional patents pending.

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Specifications* TruWave Disposable Pressure Transducer				
Operating Temperature Range	15° to 40°C			
Storage Temperature Range	-25° to +70°C			
Sensitivity	5.0µ V/V/mmHg ± 1%			
Nonlinearity and Hysteresis	± 1.5% of reading or ± 1 mmHg, whichever is greater			
Excitation Impedance	350 ohms ± 10% with typical Edwards Monitor Cable attached			
Signal Impedance	300 ± 5%			
Zero Offset	≤ ± 25 mmHg			
Zero Thermal Drift	≤ ± 0.3 mmHg/°C			
Output Drift	± 1 mmHg per 8 hours after 20 second warm-up			
Sensitivity Thermal Drift	≤ ± 0.1%/°C			
Natural Frequency	40 Hz nominal for a standard kit (48"/12"); >200 Hz for transducer alone			
Defibrillator Challenge	withstands 5 repeated discharges of 360 Joules wilthin 5 minutes delivered into a 50 ohm load			
Leakage Current	<2µ amps at 120V RMS 60 Hz			
Overpressure Tolerance	-500 to +5000 mmHg			
Shock Resistance	withstands 3 drops from 1 meter			
Light Sensitivity	< 1 mmHg at 6 volts excitation when exposed to a 3400°K tungsten light source at 3000 fool candles			
Volumetric Displacement	≤ 0.03 mm³/100 mmHg for transducer without flush device			
Flow rate across flush device with IV bag pressurized to 300 mmHg Blue Snap-Tab device Yellow Snap-Tab device	3 ± 1 mVhr 30 ± 10 mVhr			

^{*}at 6.00VDC and 25°C unless otherwise stated.

All specifications meet or exceed the AAMI Standard for performance interchangeability of resistance bridge type blood pressure transducers.

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Appendix D

Drawings











Appendix E

Performance Testing Reports





Appendix F

Clinical Testing Report

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Appendix G

Biocompatibility Testing Reports

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Appendix H

Hazard Analysis



Appendix I

Product Software Development Procedure



Appendix J

Software Requirements Specification



$\boldsymbol{Appendix}\;\boldsymbol{K}$

Software Design Document

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Appendix L

Software Testing Reports

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Appendix M

Trace Matrix

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Appendix N

Mechanical and Environmental

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Appendix O

EMC Testing Report



Appendix P

Reference Articles

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STATISTICAL METHODS FOR ASSESSING AGREEMENT BETWEEN TWO METHODS OF CLINICAL MEASUREMENT

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Summary In clinical measurement comparison of a new measurement technique with an established one is often needed to see whether they agree sufficiently for the new to replace the old. Such investigations are often analysed inappropriately, notably by using correlation coefficients. The use of correlation is misleading. An alternative approach, based on graphical techniques and simple calculations, is described, together with the relation between this analysis and the assessment of repeatability.

INTRODUCTION

CLINICIANS often wish to have data on, for example, cardiac stroke volume or blood pressure where direct measurement without adverse effects is difficult or impossible. The true values remain unknown. Instead indirect methods are used, and a new method has to be evaluated by comparison with an established technique rather than with the true quantity. If the new method agrees sufficiently well with the old, the old may be replaced. This is very different from calibration, where known quantities are measured by a new method and the result compared with the true value or with measurements made by a highly accurate method. When two methods are compared neither provides an unequivocally correct measurement, so we try to assess the degree of agreement. But how?

The correct statistical approach is not obvious. Many studies give the product-moment correlation coefficient (t) between the results of the two measurement methods as an indicator of agreement. It is no such thing. In a statistical journal we have proposed an alternative analysis, and clinical colleagues have suggested that we describe it for a medical readership.

Most of the analysis will be illustrated by a set of data (table) collected to compare two methods of measuring peak expiratory flow rate (PEFR).

SAMPLE DATA

The sample comprised colleagues and family of J. M. B. chosen to give a wide range of PEFR but in no way representative of any defined population. Two measurements were made with a Wright peak flow meter and two with a mini Wright meter, in random order. All measurements were taken by J. M. B. using the same two instruments. (These data were collected to demonstrate the statistical method and provide no evidence on the comparability of these two instruments.) We did not repeat suspect readings and took a single reading as our measurement of PEFR. Only the first measurement by each method is used to illustrate the comparison of methods, the second measurements being used in the study of repeatability.

PEER MEASURED WITH WRIGHT PEAK FLOW AND MINI WRIGHT PEAK FLOW METER

ioardu	Wright peak flow meter		Mini Wright peak flow meter	
	First PEFR (Fmin)	Second PEFR (i/mm)	First PEFR (Umin)	Second PEFR (Vmin)
1	494	490	512	525
2	395	397	4 30	415
3	516	512	520	508
4	434	401	428	444
5	476	470	500	500
6	557	61!	600	625
7	413	415	364	460
8	442	431	380	390
9	650	638	658	647
01	433	429	445	432
11	417	420	432	420
12	656	633	626	605
13	267	275	260	2 27
14	478	492	477	467
15	178	165	259	268
16	423	372	350	370
17	427	421	451	443

PLOTTING DATA

The first step is to plot the data and draw the line of equality on which all points would lie if the two meters gave exactly the same reading every time (fig 1). This helps the eye in gauging the degree of agreement between measurements, though, as we shall show, another type of plot is more informative.

INAPPROPRIATE USE OF CORRELATION COEFFICIENT

The second step is usually to calculate the correlation coefficient (r) between the two methods. For the data in fig 1, r=0.94 (p<0.001). The null hypothesis here is that the measurements by the two methods are not linearly related. The probability is very small and we can safely conclude that PEFR measurements by the mini and large meters are related. However, this high correlation does not mean that the two methods agree:

(1) measures the strength of a relation between two variables, not the agreement between them. We will have perfect agreement only if the points in fig. I lie along the line of equality, but we will have perfect correlation if the points lie along any straight line.

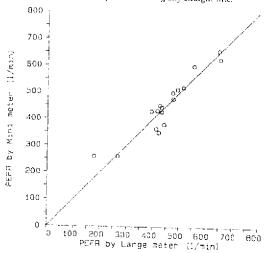


Fig 1—PEFR measured with large Wright peak flow meter and mini Wright peak flow meter, with line of equality.

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(2) A change in scale of measurement does not affect the correlation, but it certainly affects the agreement. For example, we can measure subcutaneous fat by skinfold calipers. The calipers will measure two thicknesses of fat. If we were to plot calipers measurement against half-calipers measurement, in the style of fig 1, we should get a perfect straight line with slope 2.0. The correlation would be 1.0, but the two measurements would not agree—we could not mix fat thicknesses obtained by the two methods, since one is twice the other.

- (3) Correlation depends on the range of the true quantity in the sample. If this is wide, the correlation will be greater than if it is narrow. For those subjects whose PEFR (by peak flow meter) is less than 500 l/min, r is 0.88 while for those with greater PEFRs r is 0.90. Both are less than the overall correlation of 0.94, but it would be absurd to argue that agreement is worse below 500 l/min and worse above 500 l/min than it is for everybody. Since investigators usually try to compare two methods over the whole range of values typically encountered, a high correlation is almost guaranteed.
- (4) The test of significance may show that the two methods are related, but it would be amazing if two methods designed to measure the same quantity were not related. The test of significance is irrelevant to the question of agreement.
- (5) Data which seem to be in poor agreement can produce quite high correlations. For example, Serfontein and Jaroszewicz² compared two methods of measuring gestational age. Babies with a gestational age of 35 weeks by one method had gestations between 34 and 39.5 weeks by the other, but r was high (0.85). On the other hand, Oldham et al³ compared the mini and large Wright peak flow meters and found a correlation of 0.992. They then connected the meters in series, so that both measured the same flow, and obtained a "material improvement" (0.996). If a correlation coefficient of 0.99 can be materially improved upon, we need to rethink our ideas of what a high correlation is in this context. As we show below, the high correlation of 0.94 for our own data conceals considerable lack of agreement between the two instruments.

MEASURING AGREEMENT

It is most unlikely that different methods will agree exactly, by giving the identical result for all individuals. We want to know by how much the new method is likely to differ from the old; if this is not enough to cause problems in clinical interpretation we can replace the old method by the new or use the two interchangeably. If the two PEFR meters were unlikely to give readings which differed by more than, say, 10 l/min, we could replace the large meter by the mini meter because so small a difference would not affect decisions on patient management. On the other hand, if the meters could differ by 100 l/min, the mini meter would be unlikely to be satisfactory. How far apart measurements can be without causing difficulties will be a question of judgment. Ideally, it should be defined in advance to help in the interpretation of the method comparison and to choose the sample size.

The first step is to examine the data. A simple plot of the results of one method against those of the other (fig. 1) though without a regression line is a useful start but usually all the data points will be clustered near the line and it will be difficult to assess between-method differences. A plot of the difference between the methods against their mean may be more informative. Fig 2 displays considerable lack of agreement between the large and mini meters, with discrepancies of up to 80 l/min; these differences are not obvious from fig 1. The plot of difference against mean also allows us to investigate any possible relationship between the measurement error and the true value. We do not know the true value, and the mean of the two measurements is the best estimate we have. It would be a mistake to plot the difference against either value separately because the difference will be related to each, a well-known statistical artefact."

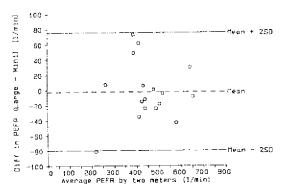


Fig 2-Difference against mean for PEFR data.

For the PEFR data, there is no obvious relation between the difference and the mean. Under these circumstances we can summarise the lack of agreement by calculating the bias, estimated by the mean difference (d) and the standard deviation of the differences (s). If there is a consistent bias we can adjust for it by subtracting a from the new method. For the PEFR data the mean difference (large meter minus small meter) is -2-1 1/min and s is 38-8 1/min. We would expect most of the differences to lie between 3-2s and 3+2s (fig 2). If the differences are Normally distributed (Gaussian), 95% of differences will lie between these limits (or, more precisely, between d-1.96s and d+1.96s). Such differences are likely to follow a Normal distribution because we have removed a lot of the variation between subjects and are left with the measurement error. The measurements themselves do not have to follow a Normal distribution, and often they will not. We can check the distribution of the differences by drawing a histogram. If this is skewed or has very long tails the assumption of Normality may not be valid (see below).

Provided differences within \$\frac{1}{2}\$s would not be clinically important we could use the two measurement methods interchangeably. We shall refer to these as the "limits of agreement". For the PEFR data we get:

$$d-2s = -2 \cdot 1 + (2 \times 38 \cdot 8) = -79 \cdot 7 \text{ 1/min}$$

 $d+2s = -2 \cdot 1 + (2 \times 38 \cdot 8) = 75 \cdot 5 \text{ 1/min}$

Thus, the mini meter may be 80 l/min below or 76 l/min above the large meter, which would be unacceptable for clinical purposes. This lack of agreement is by no means obvious in fig 1.

PRECISION OF ESTIMATED LIMITS OF AGREEMENT

The limits of agreement are only estimates of the values which apply to the whole population. A second sample would give different limits. We might sometimes wish to use standard errors and confidence intervals to see how precise our estimates are, provided the differences follow a distribution which is approximately Normal. The standard error of d is $\sqrt{(s^2/n)}$, where n is the sample size, and the standard error of d-2s and d+2s is about $\sqrt{(3s^2/n)}$. 95% confidence intervals can be calculated by finding the appropriate point of the t distribution with n-1 degrees of freedom, on most tables the column marked 5% or 0-05, and then the confidence interval will be from the observed value minus t standard errors to the observed value plus t standard errors.

For the PEFR data s = 38.8. The standard error of 3 is thus 9.4. For the 95% confidence interval, we have 16 degrees of freedom and

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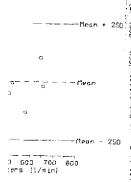
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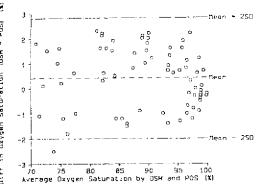


Fig 3-Oxygen saturation monitor and pulsed oximeter saturation.

 $t=2\cdot 12$. Hence the 95% confidence interval for the bias is $-2\cdot 1-(2\cdot 12\times 9\cdot 4)$ to $-2\cdot 1+(2\cdot 12\times 9\cdot 4)$, giving $-22\cdot 0$ to $17\cdot 8$ l/min. The standard error of the limit $\overline{d}-2s$ is $16\cdot 3$ l/min. The 95% confidence interval for the lower limit of agreement is $-79\cdot 7-(2\cdot 12\times 16\cdot 3)$ to $-79\cdot 7+(2\cdot 12\times 16\cdot 3)$, giving $-114\cdot 3$ to $-45\cdot 1$ l/min. For the upper limit of agreement the 95% confidence interval is $40\cdot 9$ to $110\cdot 1$ l/min. These intervals are wide, reflecting the small sample size and the great variation of the differences. They show, however, that even on the most optimistic interpretation there can be considerable discrepancies between the two meters and that the degree of agreement is not acceptable.

EXAMPLE SHOWING GOOD AGREEMENT

Fig 3 shows a comparison of oxygen saturation measured by an oxygen saturation monitor and by pulsed oximeter saturation, a new non-invasive technique. Here the mean difference is 0.42 percentage points with 95% confidence interval 0.13 to 0.70. Thus pulsed oximeter saturation tends to give a lower reading by between 0.13 and 0.70. Despite this, the limits of agreement (-2.0 and 2.8) are small enough for us to be confident that the new method can be used in place of the old for clinical purposes.

RELATION BETWEEN DIFFERENCE AND MEAN

In the preceding analysis it was assumed that the differences did not vary in any systematic way over the range of measurement. This may not be so, Fig 4 compares the measurement of mean velocity of circumferential fibre shortening (VCF) by the long axis and short axis in M-mode echocardiography. The scatter of the differences increases as the VCF increases. We could ignore this but the limits of

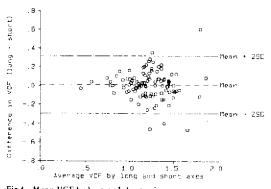


Fig 4—Mean VCF by long and short axis measurements.

agreement would be wider apart than necessary for small VCF and narrower than they should be for large VCF. If the differences are proportional to the mean, a logarithmic transformation should yield a picture more like that of figs 2 and 4, and we can then apply the analysis described above to the log-transformed data.

Fig 5 shows the log-transformed data of fig 4. This still shows a relation between the difference and the mean VCF, but there is some improvement. The mean difference is -0.008 on the log scale and the limits of agreement are -0.226 and 0.243. However, although there is only negligible bias, the limits of agreement have somehow to be related to the original scale of measurement. If we take the antilogs of these limits we get 0.80 and 1.27. However, the antilog of the difference between two values on a log scale is a dimensionless ratio. The limits tell us that for about 95% of cases the short axis measurement of VCF will be between 0.80 and 1.27 times the long axis measurement by 20% below to 27% above. (The log transformation is the only transformation giving backtransformed differences which are easy to interpret, and we do not recommend the use of any other in this context.)

Sometimes the relation between difference and mean is more complex than that shown in fig 4 and log transformation does not work. Here a plot in the style of fig 2 is very helpful in comparing the methods. Formal analysis, as described above, will tend to give limits of agreement which are too far apart rather than too close, and so should not lead to the acceptance of poor methods of measurement.

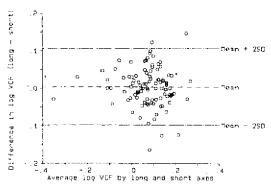


Fig 5-Data of fig 4 after togarithmic transformation.

REPEATABILITY

Repeatability is relevant to the study of method comparison because the repeatabilities of two methods of measurement limit the amount of agreement which is possible. If one method has poor repeatability—ie, there is considerable variation in repeated measurements on the same subject—the agreement between the two methods is bound to be poor too. When the old method is the more variable one, even a new method which is perfect will not agree with it. If both methods have poor repeatability, the problem is even worse.

The best way to examine repeatability is to take repeated measurements on a series of subjects. The table shows paired data for PEFR. We can then plot a figure similar to fig 2, showing difference against mean for each subject. If the differences are related to the mean, we can apply a log transformation. We then calculate the mean and standard deviation of the differences as before. The mean difference

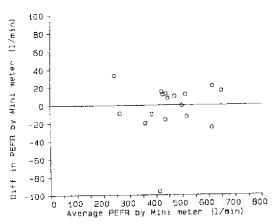


Fig 6-Repeated measures of PEFR using mini Wright peak flow

should here be zero since the same method was used. (If the mean difference is significantly different from zero, we will not be able to use the data to assess repeatability because either knowledge of the first measurement is affecting the second or the process of measurement is altering the quantity.) We expect 95% of differences to be less than two standard deviations. This is the definition of a repeatability coefficient adopted by the British Standards Institution.7 If we can assume the mean difference to be zero this coefficient is very simple to estimate: we square all the differences, add them up, divide by n, and take the square root, to get the standard deviation of the differences.

Fig 6 shows the plot for pairs of measurements made with the mini Wright peak flow meter. There does not appear to be any relation between the difference and the size of the PEFR. There is, however, a clear outlier. We have retained this measurement for the analysis, although we suspect that it was technically unsatisfactory. (In practice, one could omit this subject.) The sum of the differences squared is 13 479 so the standard deviation of differences between the 17 pairs of repeated measurements is 28.2 l/min. The coefficient of repeatability is twice this, or 56.4 I/min for the mini meter. For the larger meter the coefficient

If we have more than two repeated measurements the calculations are more complex. We plot the standard deviation of the several measurements for that subject against their mean and then use one-way analysis of variance,8 which is beyond the scope of this article,

MEASURING AGREEMENT USING REPEATED MEASUREMENTS

If we have repeated measurements by each of two methods on the same subjects we can calculate the mean for each method on each subject and use these pairs of means to compare the two methods using the analysis for assessing agreement described above. The estimate of bias will be unaffected, but the estimate of the standard deviation of the differences will be too small, because some of the effect of repeated measurement error has been removed. We can correct for this. Suppose we have two measurements obtained by each method, as in the table. We find the standard deviations of differences between repeated measurements for each method separately, s1 and s2, and the standard deviation of the differences between the means for each method, s_D . The corrected standard deviation of differences, s_a , is $\sqrt{(s_D^2 + \frac{1}{2}s_1^2 + \frac{1}{2}s_2^2)}$. This is approximately $\sqrt{(2s_D^2)}$, but if there are differences between the two methods not explicable by repeatability errors alone (ie, interaction between subject and measurement method), this approximation may produce an overestimate. For the PEFR we have $s_0 = 33 \cdot 2$, $s_1 = 21 \cdot 6$, $s_c = 28 \cdot 2$ l/min. s_c is thus $\sqrt{(33 \cdot 2^2 + 1/4 \times 21 \cdot 6^2 + 1/4 \times 28 \cdot 2^2)}$ or $37 \cdot 7$ l/min. Compare this with the estimate 38.8 Umin which was obtained using a single measurement. On the other hand, the approximation $\sqrt{2s_D^2}$ gives an overestimate (47.0 l/min).

DISCUSSION

In the analysis of measurement method comparison data neither the correlation coefficient (as we show here) nor techniques such as regression analysis1 are appropriate. We suggest replacing these misleading analyses by a method that is simple both to do and to interpret. Further, the same method may be used to analyse the repeatability of a single measurement method or to compare measurements by two

Why has a totally inappropriate method, the correlation coefficient, become almost universally used for this purpose? Two processes may be at work here—namely, pattern recognition and imitation. A likely first step in the analysis of such data is to plot a scatter diagram (fig 1). A glance through almost any statistical textbook for a similar picture will lead to the correlation coefficient as a method of analysis of such a plot, together with a test of the null hypothesis of no relationship. Some texts even use pairs of measurements by two different methods to illustrate the calculation of r. Once the correlation approach has been published, others will read of a statistical problem similar to their own being solved in this way and will use the same technique with their own data. Medical statisticians who ask "why did you use this statistical method?" will often be told "because this published paper used it". Journals could help to rectify this error by returning for reanalysis papers which use incorrect statistical techniques. This may be a slow process. Referees, inspecting papers in which two methods of measurement have been compared, sometimes complain if no correlation coefficients are provided, even when the reasons for not doing so are

We thank many of our colleagues for their interest and assistance in the study of measurement method comparison, including Dr David Robson who first brought the problem tons; Dr P. D'Arbela and Dr H. Seeley for the use of their data; and Mrs S. Stevens for typing the manuscript.

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Publications, 1971; chap 7

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From:	Reviewer(s) - Name(s) SKLAPPALATACN
Subject:	510(k) Number K043065
To:	The Record - It is my recommendation that the subject 510(k) Notification:
_	The found to account
	Refused to accept. Requires additional information (other than refuse to accept).
	Is substantially equivalent to marketed devices.
• •	INOT substantially equivalent to marketed devices.
	Other (e.g., exempt by regulation, not a device, duplicate, etc.)
L	Tomer (c.g., exempt by regulation, not a devise, dapheate, etc.)
I:	s this device subject to Section 522 Postmarket Surveillance?
	s this device subject to the Tracking Regulation?
	Was clinical data necessary to support the review of this 510(k)?
I	s this a prescription device?
,	Was this 510(k) reviewed by a Third Party?
	Special 510(k)?
A	Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES YO
7 	Fruthful and Accurate Statement Requested Enclosed
\r \r	A 510(k) summary OR DA 510(k) statement
NA	The required certification and summary for class III devices
V	The indication for use form
(Combination Product Category (Please see algorithm on H drive 510k/Boilers)
	Animal Tissue Source YES NO Material of Biological Origin YES NO
٦	The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
□ No C	Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days
	De de Code (a) with monel (antional):
Predicat	Product Code with class: Additional Product Code(s) with panel (optional):
74/2	SRS / # / 21 GFR 870.2850
, ,	60 MM: (EUB 01/10/05
	(Branch Code) (Date)
	h-45
	Final Review: 7 / 1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1









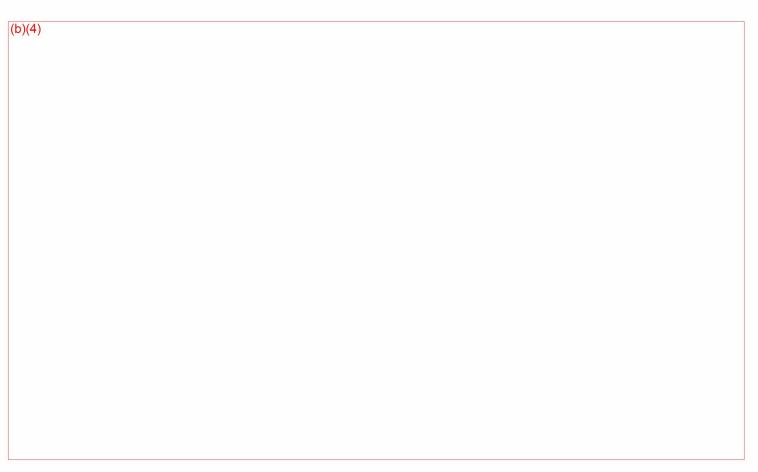


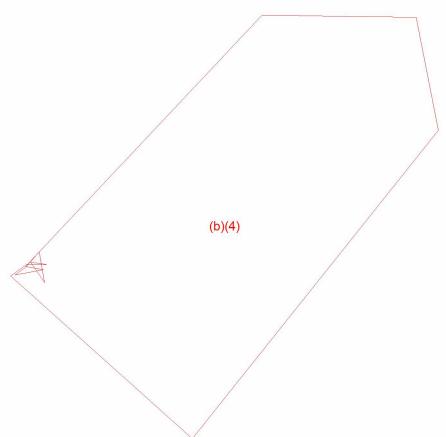












Internal Administrative Form

	YES	NO
Did the firm request expedited review?		_
2 Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP		
purposes?		
4. If, not, has POS been notified?		<u> </u>
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7 Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE		
decision?	İ	
9. If yes, does this new 510(k) address the NSE issue(s), (e.g.,		
performance data)?		
10. Are you aware of the submitter being the subject of an integrity		
investigation?	1	
11 If yes consult the ODE Integrity Officer.		1
12 Has the ODE Integrity Officer given permission to proceed with the		
review? (Blue Book Memo #l91-2 and Federal Register 90N0332,		Ī
September 10, 1991.		<u> </u>

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: (045065					
The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):					
	Special 510(k)	-	Do Sections 1 and 2		
	Abbreviated 510(k)	-	Do Sections 1, 3 and 4		
ď	Traditional 510(k) or t	10 ident	ification provided	-	Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or	Missing or
	Adequate	Inadequate
Cover letter, containing the elements listed on page 3-2 of the		
Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and		
Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status		
(Class I Class II Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the		
Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the		
premarket submission.		<u> </u>
Substantial Equivalence Comparison, including comparisons of		
the new device with the predicate.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including		1
diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of	,/	
the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k)		
notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

17

	Present	Inadequate
		or Missing
Name and 510(k) number of the submitter's own, unmodified		
predicate device.		
A description of the modified device and a comparison to the		
sponsor's predicate device.		
A statement that the intended use(s) and indications of the	,	1
modified device as described in its labeling are the same as the		
intended uses and indications for the submitter's unmodified		
predicate device.		
Reviewer's confirmation that the modification has not altered the		
fundamental scientific technology of the submitter's predicate		
device		1
A Design Control Activities Summary that includes the following		1000
elements (a-c):	jar sakara	
a Identification of Risk Analysis method(s) used to assess the		
impact of the modification on the device and its components, and		
the results of the analysis.		
b Based on the Risk Analysis, an identification of the required		'
verification and validation activities, including the methods or		
tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes		!
the following statements:		
A statement that, as required by the risk analysis, all		
verification and validation activities were performed by the	1	
designated individual(s) and the results of the activities		
demonstrated that the predetermined acceptance criteria were		
met. This statement is signed by the individual responsible		
for those particular activities.		
A statement that the manufacturing facility is in conformance		
with the design control procedure requirements as specified		
in 21 CFR 820.30 and the records are available for review.		
This statement is signed by the individual responsible for		
those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or		
special control(s), a summary report that describes how the		
guidance and/or special control(s) was used to address the risks		
associated with the particular device type. (If a manufacturer		
elects to use an alternate approach to address a particular risk,		
sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a		
declaration of conformity [For a listing of the required elements		
of a declaration of conformity, SEE Required Elements for a		
Declaration of Conformity to a Recognized Standard, which	ļ	
is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a	Ì
declaration of conformity, a statement that the manufacturer	
intends to conform to a recognized standard and that supporting	
data will be available before marketing the device.	
For a submission, which relies on a non-recognized standard that	
has been historically accepted by FDA, a statement that the	
manufacturer intends to conform to a recognized standard and	
that supporting data will be available before marketing the device.	
For a submission, which relies on a non-recognized standard that	
has not been historically accepted by FDA, a statement that the	
manufacturer intends to conform to a recognized standard and	
that supporting data will be available before marketing the device	
and any additional information requested by the reviewer in order	
to determine substantial equivalence.	
Any additional information, which is not covered by the guidance	
document, special control, recognized standard and/or non-	
recognized standard, in order to determine substantial	1
	1
equivalence.	

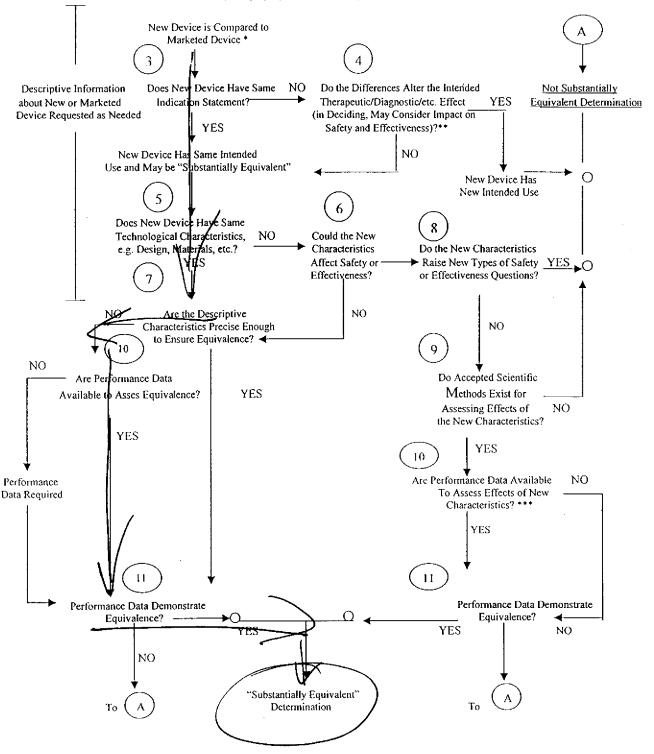
- When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	/	
b) Sterilization and expiration dating information:	V	
i) sterilization process ii) validation method of sterilization process		
iii) SAL iv) packaging y) specify pyrogen free		
vi) ETO residues vii) radiation dose viii) Traditional Method o r New Traditional Metho d		
c) Software Documentation:	~	

s) Software Documentation.	
Items with checks in the "Present or Adequate" columninformation from the sponsor. Items with checks in the column must be submitted before substantive review of Passed ScreeningYesNo Reviewer:No	e "Missing of Inadequate"
Concurrence by Review Branch:	
Date:	

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.